Patient Safety Advisory

Veterans Health Administration Warning System
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Item: **Bleeding episodes during dialysis**

Specific Information: The VA National Center for Patient Safety (NCPS) has analyzed 47 RCA (Root Cause Analysis) and Safety reports of bleeding during dialysis which occurred in VA dialysis centers from March 1, 2002, through April 30, 2008. (See attachment for full report). Forty of these events were serious bleeding episodes and some of these resulted in fatalities.

General Information: VA dialysis centers performed more than 2.5 million chronic and acute dialysis treatments during the period of time reviewed. In addition to the review of RCA and Safety reports, the nurse-managers of 65 VA dialysis centers were interviewed by telephone as were some Patient Safety Managers.

All of the significant bleeding events involved dislodgement of the venous needle or disconnection of the venous blood line at the dialysis catheter connection. In the majority of these cases, the venous pressure alarm on the dialysis machine failed to detect the event until significant blood loss had occurred. There appeared to be no statistical difference in the reported adverse bleeding events between the four brands and multiple models of dialysis machines involved, although the number of incidents with each machine may have been too small to draw any firm conclusions.

Two major risk factors for bleeding during dialysis were found: 1) 75% of the most severe bleeds occurred in patients who were restless, confused, agitated, or uncooperative, and 12.5% in patients who were asleep; 2) approximately 50% of the severe bleeds occurred outside of the chronic dialysis unit (in the ICU or in isolation rooms).

In 50% of the severe bleeds, the access site was not visible at the time of the event, and in the remaining 50%, the visibility of the access site was not documented in the RCA.

Taping of the access site and restraint policies and procedures varied across the 65 VA dialysis centers. Many dialysis machines also lacked an internal memory for alarms and shutdowns.

In addition to these findings, usability testing of the Redsense portable alarm—an FDA-approved device specifically designed to detect venous needle dislodgement during dialysis—was performed. Problems were found with the clip and the sensor connection. The manufacturer is

currently redesigning the clip and problems with the sensor connection appear to have been solved.

Recommendations:

1. It should be emphasized to all dialysis personnel and to the patients that the access site must remain visible, even though this may require some ingenuity, such as in the case of groin access or treatments done outside of the chronic dialysis unit. And, since venous pressure alarms are not consistently reliable in detecting venous disconnections before a significant amount of blood is lost, the patient should not be placed alone in a situation where the access site cannot be seen, such as rooms which do not permit ongoing observation of the blood lines. Isolation rooms should be designed or modified to allow easy visualization of the patient during treatment.

2. When possible ensure that new hemodialysis machines have an event memory for alarms and shutdowns to clarify events leading up to and during bleeding episodes.

3. HemoSafe patient connector clips should be used whenever possible to decrease the possibility of loosening or disconnection of the return blood line at the dialysis catheter.

4. The deficiencies noted in the usability study of the Redsense alarm should not preclude the use of this device on high-risk patients (i.e., confused, demented, uncooperative patients or those undergoing dialysis outside of the chronic dialysis unit).

5. It should be emphasized to all dialysis personnel that the venous pressure monitor in the dialysis machine cannot always be relied upon for the early detection of a venous line disconnection or needle dislodgment. Of the patients reported with significant bleeding on dialysis, in only 2 instances were the dialysis venous pressure alarms known to have been overridden, inactivated, or defective.

Additional Information: A complete report on Bleeding during Dialysis is attached which contains additional suggestions on taping and data to improve future RCAs on dialysis adverse events.

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ATTACHMENT

Bleeding during Dialysis
National Center for Patient Safety

Summary

From March 1, 2002 until April 30, 2008, VHA dialysis centers have performed more than 2,500,000 acute and chronic dialysis treatments. Over that period of time, the NCPS has received 78 RCAs and Safety Reports of complications or other problems which developed while patients were undergoing hemodialysis in our facilities. Analysis of the 78 reports revealed that 47 concerned bleeding episodes which occurred during the dialysis treatment. 40 were serious bleeds and all involved dislodgement of the venous needle or disconnection of the venous blood line at the dialysis catheter attachment.

In the course of the analysis of the bleeding episodes, all RCAs and Safety Reports were reviewed and all nurse-managers of the 65 VA dialysis units were interviewed by telephone. When appropriate, PSMs were also interviewed.

Two major risk factors for bleeding during dialysis were found: patients with mental status problems such as dementia, confusion, agitation, etc., and dialysis treatments which occurred outside of the chronic dialysis unit (ICU, isolation room, etc.).

Solutions were studied to reduce these bleeding episodes: interventions to make the patients comfortable and warm without obscuring the dialysis access site; restraints, sitters, and other interventions for the individual patient considered to be at high risk; tape and taping techniques; connector clips to secure blood lines to dialysis catheters; the need for an internal event memory in all VA dialysis machines; a portable, rechargeable alarm with a disposable blood sensor for venous disconnections; and the need for better information regarding these bleeding episodes going forward. Recommendations were made based on these investigations.

Data Obtained from RCAs and Safety Reports

9 of the 78 total adverse events which occurred on dialysis were bleeding episodes with variable degrees of blood loss which resulted from removal of the dialysis catheter--usually pulled out by accident or on purpose by the patient or by a caregiver. 5 minor bleeding episodes occurred from leaks at a line connection. 17 adverse events which occurred on dialysis did not involve bleeding: falls, patient returned to the wrong floor, patient did not receive scheduled medications, vital signs not recorded, protective barriers not used, etc.

The most significant complication found in the RCAs and Safety Reports was also the most frequent: blood loss from venous needle dislodgement or from a disconnection of the venous line at a dialysis catheter attachment. This type of blood loss occurred in 47 patients over the 74 month period. Of these, 40 bleeding episodes resulted in blood loss greater than 100 ccs; many of those episodes required hospital admission and some resulted in the death of the patient.

Upon review of the RCAs and Safety Reports, the RCAs generally were found to have more detail and were done on the more serious bleeds. Because of this, the 16 RCAs were analyzed separately from the 24 Safety Reports.

In terms of mental status, the RCAs reported that 12 of the 16 patients were noted by dialysis staff to be restless, confused, agitated, uncooperative, or demented. Two patients were asleep when the event occurred, and the mental status of the 2 remaining patients was not noted.

7 of the 16 bleeding episodes documented in the RCAs occurred in an ICU, an isolation room, or a hospital room. 8 took place in the chronic dialysis unit, and the location of the remaining case was not noted.

5 of the 16 bleeds occurred with the use of an acute or chronic dialysis catheter and, in the remaining cases, the venous needle had become dislodged from the access.

In 8 of the 16 cases, the access site was documented as 'not visible' when the event occurred; in the remaining 8 cases, visibility of the access was not documented.

Most of the safety reports had little detail about the incident. Only 2 of the 24 noted whether the access was covered or not at the time of the event, and the location was documented in only 3. However, 22 of the 24 events were needle displacements and 2 were noted to be disconnections or leaks at a dialysis catheter.

Because the relatively small number of bleeds was spread over 4 brands and multiple models of hemodialysis machines, there was no statistical difference between the numbers of complications with one brand of dialysis machine and another-- and no brand of machine appeared to be able to reliably detect a disconnection and shut down 100% of the time before a significant bleed had occurred.

Some dialysis machines had event memories for alarms and shutdowns which, in some cases, yielded vital information to help clarify events for the RCA team, while other machines had no such packages.

Data Obtained from VA Dialysis Unit Staff Telephone Interviews

In addition to a review of the RCAs and Safety Reports, 64 nurse-managers and 1 head nurse of VA dialysis units were interviewed by telephone to discuss their views on the characteristics of patients at high risk for bleeding complications, specifically venous needle dislodgements and disconnections of the blood line at the dialysis catheter, and measures each unit implements to prevent this event. Each nurse was asked, "Which patients do you consider to be at high risk for venous needle dislodgement or venous line disconnection?" No leading questions were asked. Information was also obtained about the type of dialysis machine used and the number of stations in each unit.

63 of 65 centers considered confused, agitated, restless, or demented patients to be at an increased risk for this complication. Patients with increased perspiration were also considered to be at higher risk by 6 nurses, and 2 nurses stated that patients undergoing acute dialysis were at increased risk.

In terms of prevention, all 65 nurses considered good staffing to be the most important factor in the prevention of this type of complication, although there appeared to be no VA staffing guidelines for dialysis units. 64 of 65 centers also mentioned good taping techniques and keeping the access visible at all times as extremely important measures as well. 57 nurses

noted that securing lines to the patient added a needed extra measure of safety, and 24 centers mentioned that it was important that the patient leave his face uncovered during treatment.

For patients considered to be at high risk, 49 of 65 centers used extra taping, and 30 centers used a soft wrist restraint on the access arm. 24 centers also used special placement within the unit itself, 1:1 staffing, and/or a sitter for these patients. Some centers used a combination of restraints (soft wrist, Coban, Freedom Splint, Kling, Curlex, BandNet, and arm boards were among those mentioned) and other measures such as special placement and sitters. 16 centers stated that they had a no-restraint policy.

Chevron taping techniques were used in almost every unit. The type and brand of tape varied: silk, paper, Steri-Strips, etc. Virtually every type and brand of tape was used and each unit said that they had found their current tape and taping technique to be the best by experience.

49 units were asked about the use of enuresis alarms. 1 unit used them, 5 managers said that they would like to use them if they were approved for use during dialysis, and 43 managers stated that they would not use them even if these devices were approved. Objections were usually related to the extreme sensitivity of these alarms to any type of moisture which would unnecessarily increase the number of alarms in the unit, or to the fact that they were not considered necessary since significant bleeds are rare.

All of the nurse-managers and the head nurse stated that the policy in their unit was to keep the dialysis access site visible at all times during the treatment. Patients, they said, like to cover themselves, including their accesses, either for warmth, comfort, or both. Some patients liked to cover their heads so that they could sleep. Some access sites were more difficult to keep` visible, including groin catheters and some catheters in the acute setting, because of patient position or other factors.

Redsense Alarm Study

The Redsense alarm has recently been approved by the FDA for the specific purpose of early detection of venous needle dislodgment. A usability study by nurses of this device and a patient satisfaction survey were done at a VA dialysis center. Judging by the nurses' comments, the results appeared to be colored by the belief that an alarm to detect venous needle dislodgement was unnecessary, and that the dialysis machines could be relied upon to detect this complication and shut down before any significant amount of blood was lost. Possibly related to this, the majority of nurses in the study did not think that the alarm would make dialysis safer.

Some usability issues were uncovered by the study. Because this alarm was initially designed for use in Europe, the clip which secured the device to the patient was made to be attached to a Velcro band. In the United States, dialysis centers do not normally wrap anything circumferentially around the access arm. The alarm was redesigned with a magnetic clip which, the nurses and patients noted, made the alarm heavy and pulled on the patients' clothing. In addition, because of the remote possibility of interference, the alarms with magnetic clips were not used on patients who had implanted devices such as ICDs and pacemakers.

Initial problems with the attachment of the disposable sensors also gained the alarm negative evaluations from the nurses. A redesigned batch of sensors appeared to solve this problem, but not before the nurses generally became frustrated with the device.

The sterile disposable sensor of the alarm system is attached immediately above the needle insertion site and, to prevent false alarms, is designed to detect only a needle dislodgement or a substantial bleed. Slow oozing of blood distal to the sensor is not usually detected, and this led the nurses to question the efficacy of the device. When the sensors in question were returned to Redsense, it was found that the amount of blood was too insignificant to trigger the alarm.

We feel that we cannot recommend the Redsense alarm without reservations at this time. We would like to see a redesign of the attachment clip which would be light, reliable and does not include a magnet. After the redesign, we would like to retrial the device to make sure that there are no further usability issues with the alarm, the alarm clips, and the sensor attachments.

Recommendations/Suggestions

1. It should be noted that while keeping the access visible at all times is a standard practice in all VA hemodialysis units, in one-half of the patients whose significant bleeding episodes triggered an RCA, the access was not visible at the time of the event. It should be emphasized to all dialysis personnel and to the patients that the access must remain visible, even though this may require some ingenuity, such as in the case of groin access or treatments done outside of the chronic dialysis unit.

Loose mittens, blankets (including 1/2 and 1/4 blankets for arranging above or below access sites), appropriate and safe warming devices and cushions and whatever else is needed to keep patients warm and comfortable should be obtained for the dialysis unit. Most units stated that they preferred that patients not cover their eyes during the treatment, so sleep masks would not usually be recommended.

Since the venous pressure alarms are not consistently reliable in detecting venous disconnections before a significant amount of blood is lost, the patient should not be placed alone in a situation where the access cannot be seen, such as rooms which do not permit ongoing vigilance of the blood lines. Isolation rooms should be designed or modified to allow easy visualization of the patient during treatment. 7 of the 16 bleeding events which triggered RCAs took place outside of the chronic unit and included dialysis treatments done in the Intensive Care Unit.

2. Altered mental status also appears, from the RCAs and nurse interviews, to be a major risk factor for bleeding during dialysis. After hearing these concerns from all of the VA dialysis units, it is possible that some units may want to clarify their restraint policy. Some units have no-restraint policies, while others try to avoid the use of restraints, even though they are permitted, because of the need for orders, q 15 minute documentation, etc. This may lead to hesitation in the use of restraints when they could potentially be useful in some patients who might be considered at high risk for needle dislodgement. Some units considered a soft restraint on the access arm to be a restraint for purposes of orders and documentation, while others did not. We recommend that this issue be clarified.

3. New hemodialysis machines should have an event memory for alarms and shutdowns. In several of the RCAs, the event memory incorporated into some of the hemodialysis machines was critical in clarifying the events leading up to and during the bleeding episode.

4. The use of HemoSafe patient connector clips should be used whenever feasible to decrease the possibility of loosening or disconnection of the return blood line at the dialysis catheter.

Unfortunately, Fresenius has evaluated this clip only with the Combiset blood lines and will not sell it to facilities which do not use this tubing. We will continue to suggest to other companies that they develop a clip for their own blood tubing.

5. The deficiencies noted in the usability study of the Redsense alarm do not currently preclude the use of the device in high-risk patients should dialysis centers deem that this alarm might add an additional layer of safety to the dialysis treatment of those individuals.

6. There is no standard or best practice taping procedure for dialysis lines in the VA system, nor are there any recommendations for the best type of tape. This would seem to be fertile soil for future study by the VA dialysis units. One VA dialysis unit has recently trialed a new tape with excellent results reported by the nurses (it is soft, breathes, sticks well, tears easily) and patients (does not leave a sticky residue).

7. In many cases, RCA reports and Safety Reports lack information that could contribute to organizational leaning. To this end the following information should be provided and incorporated into RCA reports and Safety Reports when a significant bleeding episode occurs during dialysis.

a) The mental status of the patient
b) If any type of restraint was used and type of restraint
c) Location of the adverse event (chronic dialysis unit, ICU, isolation room, etc.)
d) Type (dialysis catheter, A-V fistula, graft) and location (arm, groin, etc.) of the access
e) Access covered or visible at the time of the event
f) Approximate amount of blood loss or other parameters to estimate (degree of hypotension, units of blood transfused, etc.)

8. It should be emphasized to all dialysis personnel that the venous pressure monitor in the dialysis machine cannot always be relied upon for the early detection of a venous line disconnection or needle dislodgment. Of the 40 patients reported to NCPS with significant bleeding on dialysis, in only 2 instances were the dialysis venous pressure alarms known to have been overridden, inactivated, or defective.