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Key Points

- Hemodialysis machine pressure alarms may not detect venous needle dislodgment when patients have changes in venous pressure.
- A cross-sectional analysis of hemodialysis treatment data identified the occurrences of venous pressure changes that would make it hard to trigger a machine alarm.
- A proof-of-concept use of a data analytic–derived algorithm for the detection of venous needle dislodgments was demonstrated.

Abstract

Background: In rare instances, hemodialysis venous needles may become dislodged, and when left undetected, this can lead to severe injury or death. Although dialysis machines have alarms to detect venous needle dislodgment (VND), their range of detection is limited. An understanding of the clinical conditions that may lead to missed needle dislodgments is needed for the development of more robust detection systems.

Methods: We created a sham dialysis circuit with a Fresenius 2008K dialysis machine for *in vitro* simulation testing of machine alarm behavior under variable conditions. The circuit used a blood substitute and mimicked a patient's venous access site. We varied blood flow rate, venous pressure (VP), and upward drift in VP and analyzed the time to alarm for the machine and an improved alarm algorithm. We also performed a cross-sectional retrospective study to identify the clinical occurrence of VP upward drift between September 1, 2016, and November 1, 2016, in patients on hemodialysis with an arteriovenous fistula.

Results: Of 43,390 VP readings for 147 patients on hemodialysis, 16,594 (38%) showed an upward drift in VP (range 20–79 mmHg), with a mean±SD increase of 11±18 mm Hg within 20±14 minutes. A total of 19 VND simulations under different VP and blood flow parameters resulted in 19 (100%) algorithm alarm activations. Only eight simulations (42%) activated a machine alarm, and machine alarm activation time was longer than the algorithm activation time for all eight machine alarms (range 1–13 seconds).

Conclusions: Patients can experience changes in VP during hemodialysis which may not trigger a machine alarm in the case of a VND. Our simulations showed that current dialysis machine alarm systems may not compensate for upward drift in VP, and improved algorithms for detecting needle dislodgment during hemodialysis are needed.

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Introduction

Venous needle dislodgment (VND) during hemodialysis is a rare adverse event that can cause severe injury or mortality if not detected quickly. At normal blood flow (Qb) rates of 300–500 ml/min, a VND could lead to a patient losing approximately 2 L of blood (0.5 L/min×4 min = 2 L) within only a few minutes—40% of the average human blood volume of 5 L—potentially sending the patient into hemorrhagic shock and possible exsanguination.[1] While blood loss during dialysis treatment may occur for many reasons, the Veterans Health Administration found that 85% of all

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bleeding incidents during dialysis were caused by VND.[2] Although the actual incidence of VND is difficult to estimate because of under reporting, Sandroni *et al.*[3] estimated that over 400 serious adverse events from needle dislodgement occur per year in the United States, with a 10%–30% mortality rate. A 2007 Renal Physicians Association survey of patients indicated that 3.8% of patients (12 of 318) had inadvertent needle displacement during dialysis in the prior 3 months.[4]

Transducers within dialysis machines monitor venous pressure (VP), which is detected as an aggregate of the patient's venous access pressure (VAP), the pressures created by the resistance to flow in the venous blood line and needle, and the hydrostatic pressure created by the difference in height between the location of the machine's VP transducer and the patient's access site. Notably, VP varies with changes in the patient's hematocrit and the position of the access site, and VP will increase if an outlet stenosis occurs in the access site. For patients who have arteriovenous fistulas, VAP is normally a smaller component of overall VP, and the decrease in VP that would occur after a VND could potentially be too small to trigger the dialysis machine's VP lower alarm limit, presenting a clinical vulnerability for some patients in which a VND could go undetected.

Ribitsch *et al.*[5] showed that the intra-access pressure for many patients can be lower than the dialysis machine alarm limits, especially for patients with arteriovenous fistulas, with over 70% of patients having VAP too small to trigger a machine alarm in the case of a VND. This issue can be further compounded if an upward drift of the VP occurs during dialysis due to ultrafiltration increasing the patient's hematocrit, which leads to increased blood viscosity and increased VP.[6] Any upward drift in VP during dialysis increases the pressure drop required to set off the alarm and increases the risk for an undetected VND. Although the lower alarm limit could in theory be set more conservatively (*e.g.*, 10–20 mm Hg rather than the typical 20–40 mm Hg below the VP), this narrow range could cause false machine alarms from small VP changes caused by normal clinical activities. Because the consequences of VND during hemodialysis are dire, a thorough understanding of the clinical scenarios that could lead to an undetected VND is needed.

Two examples illustrate the central problem. First, when a patient's VAP is less than the pressure difference between the patient's current VP reading and the dialysis machine's lower VP alarm limit, a VND could go undetected. Therefore, an undetected VND can occur if the patient has a low VAP (*e.g.*, patients with an arteriovenous fistula and a VAP of 10 mm Hg) and is receiving hemodialysis on a machine with the VP alarm limit set at 25 mm Hg. In this situation, if the patient's VP=200 mm Hg, the lower venous alarm limit would be activated when the VP is 200−25=175 mm Hg. However, if a VND occurs for this patient, the drop in VP because of a VND would be 200−10=190 mm Hg, which is 15 mm Hg above the lower alarm limit of 175 mm Hg, and the VND event would go undetected.

In addition, patients are at risk for undetected VND if they experience an upward drift of VP during dialysis. Note that the dynamics of the following upward drift scenario are illustrated in Figure 1 to clarify this complex problem. Thus, a patient with a starting VP of 200 mm Hg and a VAP of 40 mm Hg could experience an upward drift in VP of 30 mm Hg during a 30-minute time interval (before many machines would recalibrate to account for upward drift). If the venous lower alarm limit set on the dialysis machine is 25 mm Hg, a venous alarm will occur if the VP drops to 175 mm Hg. However, as the patient's VP drifts upward, the VP drop needed to activate the lower alarm limit would increase, until at 28 minutes; when the VP reaches 230 mm Hg, the pressure drop needed to activate the lower alarm limit is now 30+25=55 mm Hg below the current VP. If a VND occurs under these conditions, the VP would drop to 230−40=190 mm Hg, which is 190−175=15 mm Hg above the lower alarm limit of 175 mm Hg, and the VND event would go undetected.

To test our hypothesis that various VP and VAP parameters can occur in which a VND during dialysis could go undetected, we performed a retrospective medical chart review and a simulation study using a sham dialysis circuit. Our objectives were to define the possible scenarios of how a VND may go undetected during hemodialysis and to estimate how often these situations may actually occur in the dialysis clinic. First, we retrospectively investigated a cross-sectional sample of medical data to determine how often patients' VP drifted upward during dialysis; next, we created a sham dialysis circuit and performed simulations by varying several dialysis machine parameters to model machine alarm behavior and to test a novel VND detection algorithm; thus, revealing the possible scenarios in which a VND may go undetected when the VAP is less than the pressure difference between a patient's current VP reading and the dialysis machine's lower VP alarm limit.

Methods

The Institutional Review Board at Henry Ford Hospital determined that this project did not meet the definition of human subjects' research as defined by the Revised Common Rule (IRB#15821).

Upward Drift of VP in Dialysis Patients

To determine the clinical frequency of significant upward drift in VP during hemodialysis, we extracted VP data from medical records for patients who received dialysis between September 1, 2016, and November 1, 2016, from the Greenfield Health System. Because patients with fistula have lower access pressure and are more vulnerable to VND, we included patients on hemodialysis who had an arteriovenous fistula and excluded patients with hemodialysis grafts. We examined data from a 2-month period as a convenience sample that provided at least 100 patients. The number of values where VP increased from one reading to the next at the same Qb during a 30-minute interval was determined. The increase from the initial VP value to the maximum VP value during the 30-minute interval was defined as ΔVP, and the time that ΔVP occurred was defined as ΔTime. The VP data were analyzed using the following criterion: the number of treatments where ΔVP was ≥20 and <80 mm Hg starting at minute 5 and continuing to the end of the 30-minute time interval. This criterion was selected because Fresenius dialysis machines reset VP limits every 30 minutes, which allows time for the VP to drift upward. The upper limit ΔVP <80 mm Hg was selected because an increase in VP ≥80 mm Hg would activate the upper VP machine alarm.

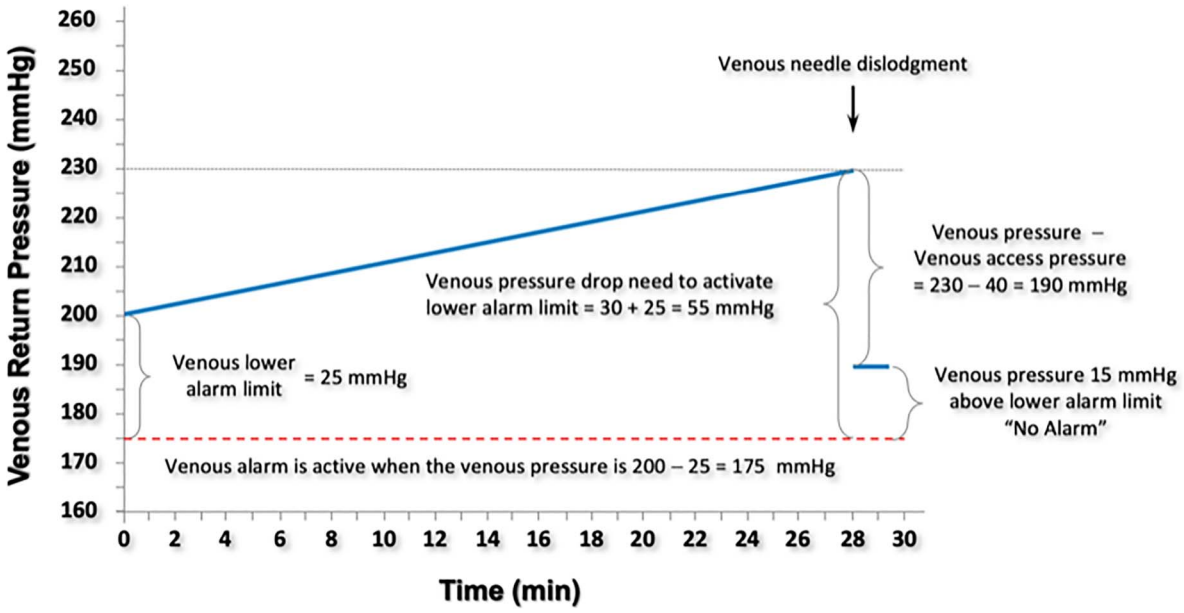

Figure 1. Example scenario of venous pressure upward drift leading to a potentially undetected venous needle dislodgment. Graph showing an upward drift in VP during a 30-minute time interval before the alarm limits are automatically reset on the dialysis machine. The lower limit for the VP is initially set at 25 mm Hg below the starting VP of 200 mm Hg at time 0, which means the lower VP alarm will be activated when the VP drops to 200−25=175 mm Hg. If the VP drifts up by 30 mm Hg to 230 at 28 minutes, VP will have to drop by 30+25=55 mm Hg below the current VP of 230 mm Hg to activate the lower venous alarm. If the patient has an access pressure of 40 mm Hg and a VND occurs at 28 minutes, the drop in VP will be 230−40=190 mm Hg or 15 mm Hg above the dialysis machine's lower venous alarm limit pressure of 175 mm Hg, resulting in an undetected VND. VND, venous needle dislodgment; VP, venous pressure.

Dialysis Circuit for the Simulation of VND

Figure 2 illustrates the sham dialysis circuit used to simulate parameters that could lead to an undetected VND. The simulated patient access site (gray, Figure 2) has a 1 L fluid reservoir (far right) that supplies blood or a glycerol solution with a viscosity equivalent to blood to two identical blood pumps that can yield a maximum flow of 1200 ml/min. Access flow was maintained at 800 ml/min through the artificial access site for all simulations to minimize pressure variations in the circuit (Figure 2). Pressure variations in the fluid flowing out of the pumps were minimized using a pressure equalization bladder (0.5 L saline bag). A section of 8-mm blood pump tubing was used to simulate the access site, which had three 15-gauge fistula needles (Medisystems) glued in place. The arterial needle on the left with the blood line passing through the blood pump was used to supply fluid to the blood compartment of the dialyzer; the venous needle to the right was connected to the venous return line; and the third needle to the far right was connected to an independent pressure transducer to monitor the VAP in the access site. The platform holding the access site could be raised or lowered to change the distance (ΔH) between the location of the VP measurement site on the dialysis machine and the level of the access site. Changing ΔH simulates variation in the height of the patient's access site in relationship to the VP measurement site, and raising the platform increases VP measured on the dialysis machine. The fluid reservoir could be raised or lowered to select any VAP over the normal range, and pressure was verified with the independent pressure transducer (Figure 2).

Test Setup

A Fresenius 2008K hemodialysis machine was used. An analog to digital data acquisition system was connected directly to the analog output of the Fresenius VP module inside the dialysis machine to obtain a continuous recording of machine VP from the digital acquisition system (VP_{DAQ}). All data recorded by the dialysis machine (VP, preblood pump arterial pressure, systolic pressure, diastolic pressure, and machine alarms) were recorded every 2 seconds from the serial port of the dialysis machine using a computer program developed with LabVIEW software (NI Corp).

For VND simulations, a glycerol solution was used in the dialysis circuit. The glycerol solution was made by mixing glycerol (176 ml) with purified water (780 ml) with a specific gravity of 1.055 (22% glycerol by weight in water at 20°C), providing a fluid with viscosity characteristics similar to whole blood.[7,8] After the glycerol solution was added to the circuit, it was adjusted by adding water or glycerol to produce a VP of 170 mm Hg at Qb of 450 ml/min. By defining the relationship between Qb, hematocrit, and VP, Frinak *et al.*[6,9] showed that whole blood with a hematocrit of 29% circulating at 450 ml/min in a similar circuit with zero access pressure and ΔH=20 cm would have a venous return pressure of 150 mm Hg, and adding a VAP of 20 mm Hg gives a final VP of 170 mm Hg.

Because glycerol has a molecular weight of 92.1 g/mol, it is easily removed by dialysis. Figure 2 shows the modifications needed to use a glycerol solution in a sham dialysis circuit. Glycerol was pumped out of the access site through the arterial needle, transported using the blood pump into dialyzer 1, and returned to the access site using the venous needle. To ensure normal machine operation, a bypass

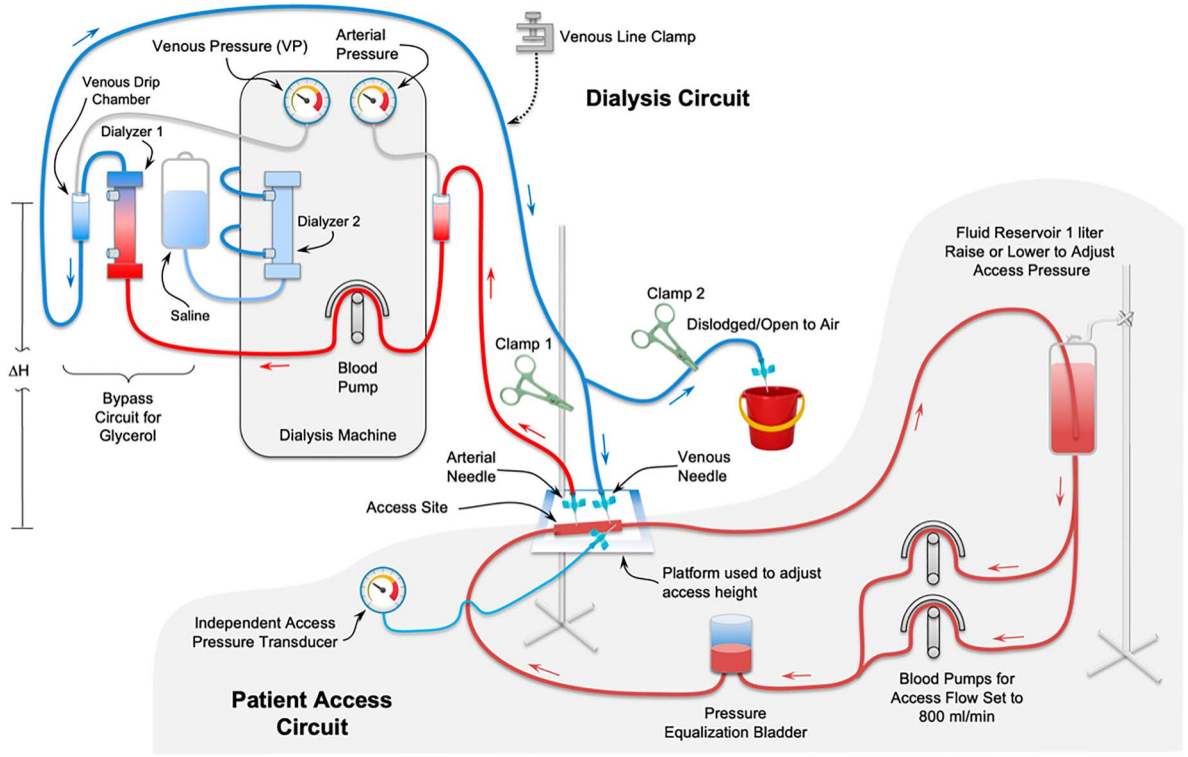

Figure 2. Model of the sham dialysis circuit. The patient side of the circuit uses two blood pumps that supply blood at up to 1200 ml/min from the reservoir. Pressure variations are minimized using a pressure equalization bladder and a section of 8-mm blood pump tubing is used to simulate the access site. The blood reservoir can be raised or lowered to select any access pressure over the desired range with the pressure being verified with an independent pressure measurement device. The dialysis machine circuit shows the modifications needed to use a glycerol solution as a substitute for blood. Glycerol is pumped out of the access site through the arterial needle and transported using the blood pump into dialyzer 1 and is returned to the access site using the venous needle. To ensure normal operation of the dialysis machine, a bypass circuit is created by connecting dialyzer 2 to the dialysate lines of the dialysis machine. The blood compartment of dialyzer 2 is filled with saline and remains connected to a 1 L saline bag, which allows the dialysis machine to remove 50 ml/h of ultrafiltration from the saline bag, minimizing transmembrane pressure alarms during sham dialysis.

circuit was created by connecting dialyzer 2 to the dialysate lines of the dialysis machine. The blood compartment of dialyzer 2 was filled with saline and remained connected to a 1 L saline bag. This allowed the dialysis machine to remove 50 ml/h of ultrafiltration from the saline bag, which minimized transmembrane pressure alarms during simulations. The circuit in Figure 2 can be used with whole blood if dialyzer 2 is removed and dialyzer 1 is connected to the dialysate lines of the dialysis machine.

Simulation of Upward Drift in VP

Figure 3 illustrates successive screen images of the VP alarm system captured during a simulated dialysis session with the Fresenius 2008K dialysis machine, which corrects the venous alarm limits for drift by recalibrating the upper and lower alarm limits every 30 minutes. Qb was set at 400 ml/min, and the starting VP was 140 mm Hg. Closing the venous line clamp (Figure 2) created a narrowing of the tubing, which restricted flow in the tubing resulting in an increased VP, simulating an upward drift in VP. Note that the dialysis machine screen displayed in intervals of only 10 mm Hg, so 115 and 100 mm Hg are the same in Figure 3, D and E. Initial VP limits automatically set by the dialysis machine are ±80 mm Hg above and below the VP at 140 mm Hg (Figure 3A). After 1 minute, the lower alarm limit was reduced from 80 to 25 mm Hg, setting the lower limit at 115 mm Hg (Figure 3B). Over the next 11 minutes, the VP was artificially increased from 140 mm Hg to 180 by gradually closing the venous line clamp to simulate VP upward drift. Note that the actual alarm limit for the VP being recorded by the machine was 65 mm Hg below the current VP of 180 mm Hg (Figure 3C). At this point, the VP would need to drop 65 mm Hg before the dialysis machine venous alarm would be activated. Alarm conditions that would require a drop of 65 mm Hg to detect VND remained the same for the next 18 minutes (Figure 3D). Alarm limits were automatically reset to ±80 mm Hg above and below 180 mm Hg 30 minutes after the initial alarm limits were set (Figure 3E), and 1 minute later, the lower limit was set to 25 mm Hg below the current VP of 180 mm Hg, setting the new lower alarm limit at 155 mm Hg (Figure 3F). Other dialysis machine manufacturers typically do not adjust the venous alarm limits at regular intervals, or they use an on-screen control to manually readjust the limits for the current VP reading. All dialysis machines reset VP alarm limits when the blood pump setting is changed or if the pump stops.

VND Simulations

To simulate a VND event, the venous return was diverted through a bifurcation in the venous return line to an additional 15-gauge dialysis needle (Figure 2). Clamp 1 was placed on the

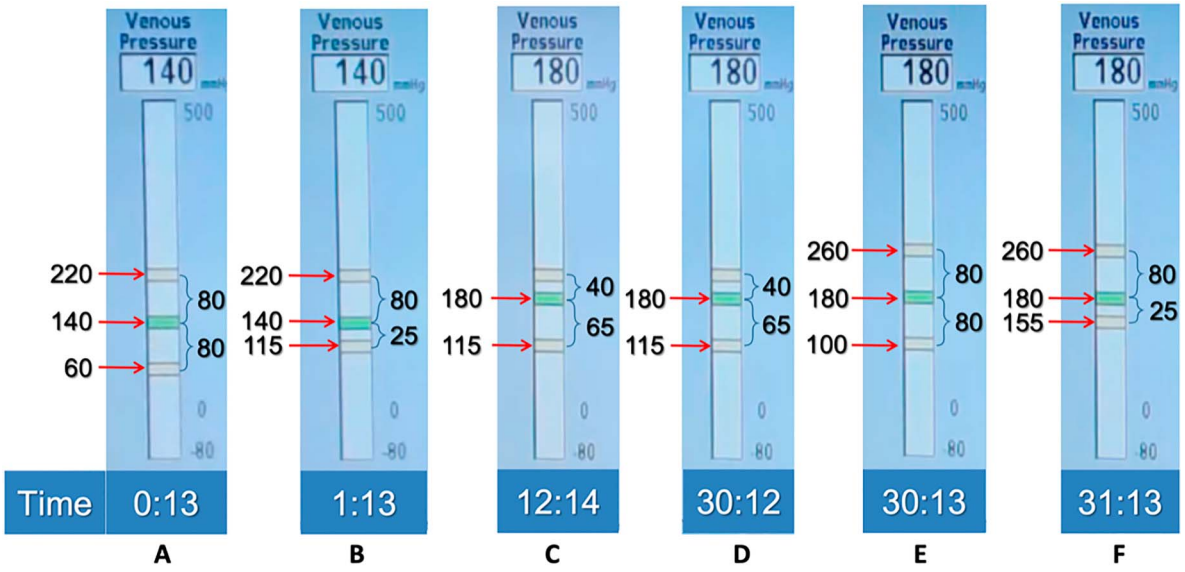

Figure 3. Data showing the operation of the dialysis machine VP alarm system over a time span of 31 minutes with blood flow 400 ml/min and a starting VP of 140 mm Hg. Initial VP limits are ±80 mm Hg (A) with a range from 60 to 220 mm Hg. (B) After 1 minute, the lower alarm limit is reduced from 80 to 25 mm Hg and the machine will alarm at 115 mm Hg. (C) Over the next 11 minutes, the VP was artificially increased to 180 mm Hg to simulate upward drift that occurs during dialysis. Note that the actual alarm limits have changed to +40 and −65 mm Hg. (D) At this point, the VP would have to drop 65 mm Hg before the dialysis machine venous alarm would be activated. Alarm conditions remained the same for the next 18 minutes. (E) Thirty minutes after the initial alarm limits were set, alarm limits were reset to ±80 mm Hg, and (F) 1 minute later, the lower limit was set to −25 mm Hg below the current VP of 180 mm Hg at 155 mm Hg. VP, venous pressure.

venous line below the bifurcation leading to the venous needle in the access site, and clamp 2 was simultaneously released, allowing fluid to flow out into open air, thus simulating a VND. Testing of the system showed that closing clamp 1 and opening clamp 2 did not produce a transient spike in the value of VP and, therefore, provided a convenient and reproducible method of creating a VND episode.

VND was simulated at dialysis machine Qb of 200, 300, 400, 450, and 500 ml/min. VP alarm conditions were evaluated first with no upward drift and then with upward drift set to 5, 10, 20, 25, 30, 35, 50, and 65 mm Hg. Upward drift in VP changed the pressure drop needed to initiate the dialysis machine VP alarm from 25 to 30, 35, 45, 50, 75, and 90 mm Hg below the current VP reading on the dialysis machine.

VND Algorithm Alarm System

In addition to the dialysis machine's standard alarm, we also tested an alternative alarm on the basis of a previously reported VND algorithm designed to detect VND.[9] The alternative alarm algorithm continuously determines the VAP and simultaneously monitors VP for a rapid decrease in slope. When a rapid decrease in slope is detected, calculation of VAP is stopped and the current value of VAP is compared with the drop in VP. If the drop in VP exceeds VAP, an alarm is produced.

Results

VP data for 147 patients who had an arteriovenous fistula over 3052 treatments with a total of 43,390 VP readings were collected. The patients' fistula locations were 1079 in the forearm left side, 293 in the forearm right side, 1281 in the upper arm left side, and 399 in the upper arm right side. A mean VAP value was determined for each treatment, and 2383 treatments had valid calculations for VAP where the average treatment VAP was greater than zero. The mean±SD of the treatment VAP values for all patients was 30.8±27.3 mm Hg (n=2383). For forearm arteriovenous fistulas, the mean was 25.6±25.0 mm Hg (n=951), and for upper arm fistulas, the mean was 34.2±27.3 mm Hg (n=1432). A total of 16,594 values (38%) were observed where ΔVP increased from one reading to the next at the same Qb. The mean increase in ΔVP was 11±18 mm Hg in 20±14 minutes (Table 1). There were 1150 treatments where ΔVP was ≥20 and <80 mm Hg starting at minute 5 and continuing to the end of the time interval ΔTime, and 980 of the total 3052 treatments (32%) met the criterion at least once. The mean ΔVP for this criterion was 35±15 mm Hg, the mean rate of increase was 2.4±1.9 mm Hg/min, and ΔVP ranged between a minimum of 20 and a maximum of 79 mm Hg (Table 2). Note that no VND occurred for any patients during the clinical data collection period.

A sham dialysis circuit was used to test the alarm behavior of a standard machine alarm and the alternative alarm algorithm (not with patient data). For simulations, Qb was varied from 200 to 500 ml/min, VAP from 10 to 40 mm Hg, and the upward drift in the VP ranged from 0 to 63 mm Hg. Table 3 presents simulated VND testing parameters, and the results for 19 simulations performed with the sham dialysis circuit. The VND alternative algorithm alarm was triggered in all 19 simulations, with 8 (42%) simulations causing activation of both the machine and VND algorithm alarms. For example, in simulation 3, at Qb 500 ml/min, VP was 185 mm Hg, VAP was 20 mm Hg, no simulated upward drift was implemented, and the dialysis machine alarmed in 8 seconds while the VND alternative algorithm alarm was activated in 6 seconds. In simulation 4, an upward drift of

Table 1. Venous pressure data for patients with an arteriovenous fistula

Clinical Variable	Value
[a]Number of patients with venous fistula	147
Total number of treatments	3052
Total number of VP values	43,390
Number of treatments with VAP >0 mm Hg	2383
VAP, mm Hg, mean±SD	30.8±27.3
VAP for forearm arteriovenous fistulas, mm Hg, mean±SD (n=951)	25.6±25.0
VAP for upper arm fistulas, mmHg, mean±SD (n=1432)	34.2±27.3
Number of values where VP increased (ΔVP) from one reading to the next at the same blood flow rate	16,594
ΔVP when VP was increasing, mm Hg, mean±SD	11±18
Time of ΔVP reading increase, min, mean±SD	20±14
Rate of increase of ΔVP, mm Hg/min, mean±SD	2.0±8

VP, venous pressure; VAP, venous access pressure; ΔVP, change in venous pressure.
[a]Patient data extracted were from September 1, 2016, to November 1, 2016. Arteriovenous fistula locations were as follows: 1079 forearm left side, 293 forearm right side, 1281 upper arm left side, and 399 upper are right side.

20 mm Hg was added to the starting VP of 205 mm Hg, resulting in activation of both the dialysis machine and VND alternative algorithm alarms at 8 and 4 seconds, respectively.

No machine alarm occurred for 11 (58%) of the simulations (Table 3). For example, in simulation 5 with VAP at 20 mm Hg, when 30 mm Hg of upward drift was added to the starting VP of 190 mm Hg, the dialysis machine alarm was not activated and the VND alternative algorithm alarm was activated in 7 seconds. In simulation 9, at Qb 450 ml/min, upward drift of 63 mm Hg, and VAP of 40 mm Hg, the machine alarm was not activated but the VND alternative algorithm alarm was activated in 8 seconds.

All five simulated VND where no upward drift in VP was added resulted in both a dialysis machine and a VND alternative algorithm alarm. For the eight simulations where both alarms were triggered, the machine alarm activation time was longer than the VND alternative algorithm alarm activation time, with a largest difference of 13 seconds (simulation 15) and a smallest difference of 1 second (simulation 17) (Table 3).

Figure 4 shows an example of one simulated VND event. The output data from the VND alternative algorithm are displayed for a 6-minute time interval, with Qb=450 ml/min and VAP adjusted to 40 mm Hg before the VND event. Figure 4A (top) shows the dialysis machine serial port data with VP initially at 200±0.4 mm Hg and the venous alarm limit set to 25 mm Hg below the starting VP at 175 mm Hg. After 1 minute and 50 seconds, the machine VP was gradually increased from 200 to 263±1.4 mm Hg before the VND event by gradually closing the venous line lamp. The increase of 63 mm Hg was within the range observed in the clinical data (max ΔVP=79 mm Hg; Table 2). During the VND event, the machine VP dropped to 184±1.3 mm Hg, a decrease of 79 mm Hg, which was 9 mm Hg less than the 263−175=88 mm Hg decrease needed to initiate a dialysis machine venous alarm. Figure 4B (lower) shows the pressures calculated by the VND alternative algorithm, where the initial VP_{DAQ} corrected for drift was initially 198±1.5 mm Hg. The VP_{DAQ} was 200±3.6 mm Hg after the upward drift correction 1 minute before the VND event. The VAP just before the VND event was 40.2±4.6 mm Hg; therefore, the lower alarm limit for the VND alternative algorithm was equal to 200 mm Hg minus the VAP 40.2, resulting in 159.8 mm Hg. The VND alternative algorithm produced an alarm 8 seconds after the start of the VND event when VP_{DAQ} decreased 78 to 122±0.8 mm Hg, which was much greater than the 40.2 mm Hg decrease required to produce an alarm.

Discussion

In this study, we showed that patients on hemodialysis with an arteriovenous fistula or graft may experience

Table 2. Hemodialysis treatment data for patients with an arteriovenous fistula

Clinical Variable	Value
[a]Number of treatments where ΔVP was ≥20 and <80 mm Hg starting at minute 5 and continuing to the end of 30 min	1150
ΔVP, mm Hg, mean±SD	35±15
ΔVP mm Hg, range (minimum and maximum)	59 (20–79)
ΔTime, min, mean±SD	18±6
Rate of VP increase, mm Hg/min, mean±SD	2.4±1.9
Number of treatments meeting criterion at least one time	980
Percentage of total treatments meeting criterion at least one time	32%

ΔVP, change in venous pressure; ΔTime, change in time; VP, venous pressure.
[a]All data below this variable are for patients meeting this criterion.

Table 3. Results of simulated venous needle dislodgment testing using the sham dialysis circuit

Simulation	Qb (ml/min)	Machine VP Start (mm Hg)	Simulated Upward Drift in VP (mm Hg)	Machine VP + Upward Drift (mm Hg)	VAP (mm Hg)	Lower Limit=Machine VP − (25 + Upward Drift) (mm Hg)	Machine Alarm	VND-A Alarm	Machine Alarm Activation Time (s)	VND-A Alarm Activation Time (s)
1	500	200	0	200	10	175=200 − 25	True	True	10	3
2	500	200	35	235	10	175=235 − 60	False	True	No alarm	4
3	500	185	0	185	20	160=185 − 25	True	True	8	6
4	500	205	20	225	20	180=225 − 45	True	True	8	4
5	500	190	30	220	20	165=220 − 55	False	True	No alarm	7
6	450	170	0	170	20	145=170 − 25	True	True	11	4
7	450	170	30	200	20	145=200 − 55	False	True	No alarm	4
8	450	190	50	240	30	165=240 − 75	False	True	No alarm	8
9	450	200	63	265	40	175=265 − 88	False	True	No alarm	8
10	400	145	0	145	10	120=145 − 25	True	True	10	4
11	400	145	20	165	10	120=165 − 45	False	True	No alarm	4
12	400	150	25	175	15	125=175 − 50	False	True	No alarm	7
13	400	145	25	170	20	120=170 − 50	False	True	No alarm	7
14	300	88	0	88	20	63=88 − 25	True	True	11	5
15	300	88	5	93	20	63=93 − 30	True	True	20	7
16	300	89	10	99	20	64=99 − 35	False	True	No alarm	6
17	200	60	0	60	30	35=60 − 25	True	True	10	9
18	200	55	5	60	20	30=60 − 30	False	True	No alarm	8
19	200	60	10	70	30	35=70 − 35	False	True	No alarm	9

Qb, blood flow rate; VP, venous pressure; VAP, venous access pressure; VND, venous needle dislodgment; VND-A, venous needle dislodgment algorithm alarm.

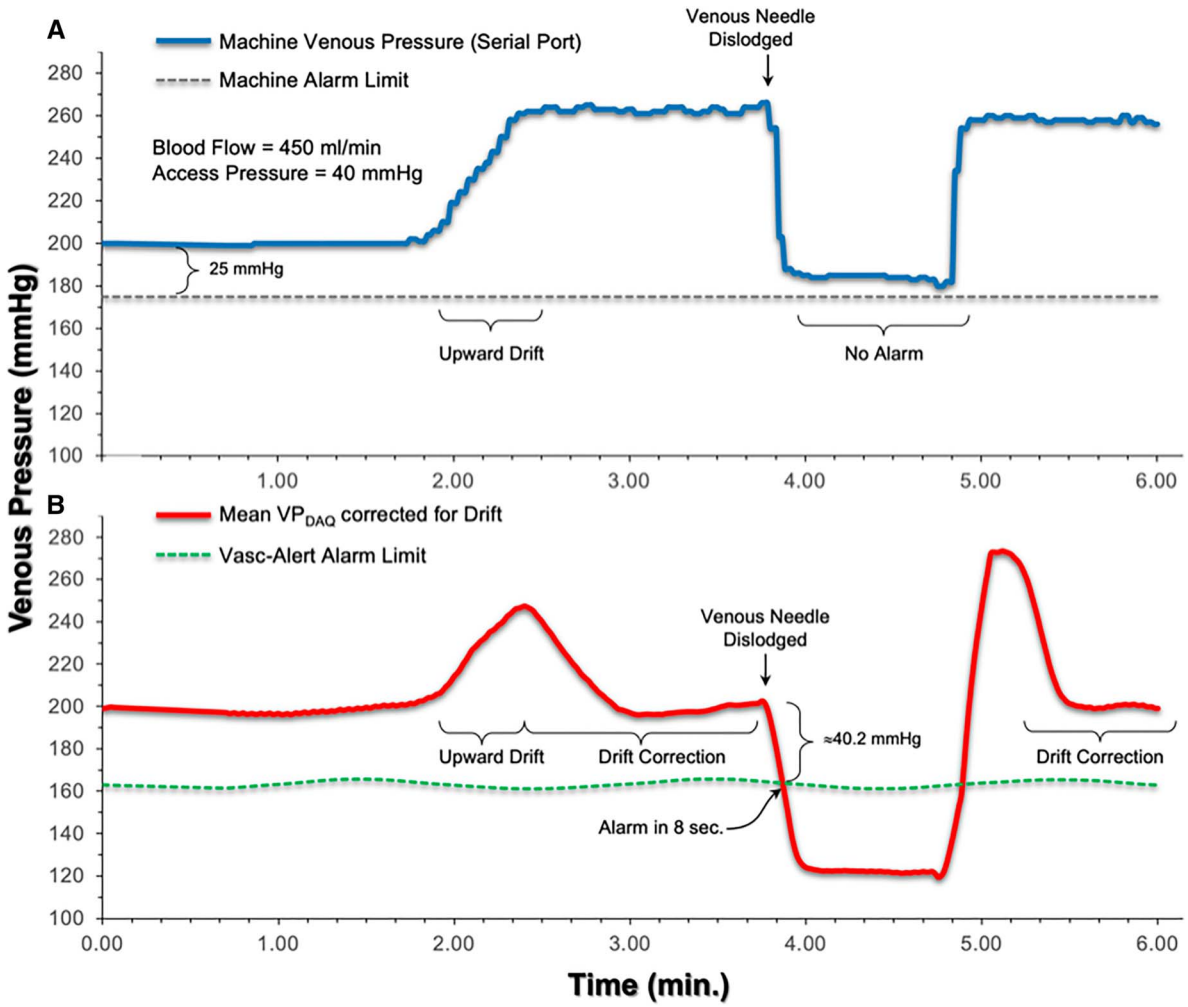

Figure 4. Example of a simulated venous needle dislodgment (VND) event using the sham circuit. The output data from the VND algorithm are displayed for a 6-minute time interval with Qb=450 ml/min and venous access pressure adjusted to 40 mm Hg before the VND event. (A) The dialysis machine data with VP initially at 200±0.4 mm Hg and the venous alarm limit set to 25 mm Hg below the starting VP at 175 mm Hg. Dialysis machine VP was gradually increased from 200 to 263±1.4 mm Hg before the VND event by gradually closing the venous line lamp. During the VND event, the machine VP dropped to 184±1.3 mm Hg, a decrease of 79 mm Hg, which was less than the 88 mm Hg decrease needed to create a dialysis machine venous alarm. (B) The pressures calculated by the VND algorithm where the initial VP_{DAQ} corrected for drift was 200±3.6 mm Hg 1 minute before the VND event. The VAP before the VND event was 40.2±4.6 mm Hg; therefore, the lower alarm limit for the VND algorithm was equal to 200 mm Hg minus the VAP 40.2=159.8 mm Hg. The VND algorithm produced an alarm 8 seconds after the start of the VND event when VP_{DAQ} decreased by 78 mm Hg to 122±0.8 mm Hg, which was much greater than the 40.2 mm Hg decrease required to produce a machine alarm. VAP, venous access pressure; VND, venous needle dislodgment; VP, venous pressure; VP_{DAQ}, VP from the digital acquisition system.

changes in VP that might not trigger a machine alarm in the occurrence of a VND, and our simulation testing with a sham dialysis circuit characterized the various clinical parameters that could lead to no dialysis machine alarm after a VND event. Our findings revealed that even at the lowest dialysis machine venous alarm limit of 20 mm Hg, 32% of the dialysis patients in our study were at an average of 55 mm Hg above the lower VP alarm limit for an extended period of time and were therefore at risk for an undetected VND. Patients on home dialysis may be at an even greater risk of VND because the process of securing the needles at the access site may vary over time, and home dialysis patients are not under the direct supervision of a trained health care provider. The VND algorithm described here would potentially provide a greater margin of safety against undetected VND if it were embedded within the dialysis machine software.

Importantly, we note that the VND alternative alarm system algorithm is not limited to detecting VND in arteriovenous fistulas. Line 9 in Table 3 shows that with a VAP of 40 mm Hg and an upward drift in VP of 63 mm Hg, the dialysis machine did not detect dislodgment of the venous needle, while dislodgment was detected by the alternative alarm system algorithm. Thus, the sham dialysis circuit simulated pressures that can feasibly occur in both arteriovenous fistulas and grafts. Ribitsch[5] reported a mean access pressure for arteriovenous grafts of 39.94±21 mm Hg (n=34); therefore, the alternative alarm system algorithm will clearly detect VND in arteriovenous grafts.

The VND alternative alarm algorithm proposed here is triggered by a rapid decrease in the VP recorded by the dialysis machine; therefore, it should be able to detect any occurrences of a separation of the venous access blood line. Further testing will be needed to incorporate the detection of blood line separations into the alternative algorithm because rapid changes in VP may also occur from patient movement, which would trigger a false positive alarm. However, any separation of the arterial blood line would introduce air into the arterial line, and air in the extracorporeal circuit is detected by the air detector in the venous return circuit, which would immediately signal the venous line clamp to close and the blood pump to stop.

The inability of dialysis machines to reliably trigger an alarm in the event of a VND has inspired the invention of several VND detection devices. The Redsense device (Redsense Medical) uses a single-use sensor patch placed near the venous needle, which is connected by an optical fiber to an alarm unit. When the patch comes into contact with blood, identified by absorption of light over a specified range of wavelengths for oxygenated to deoxygenated blood, it triggers audible and visual alarms. The US Food and Drug Administration has cleared this device for in-center and home hemodialysis use. The device is reasonably efficacious, correctly alarming for 92.5% of blood leakage cases, which increases to 97.2% when the sensor is positioned close to the puncture site.[10] However, the device significantly increases the cost of dialysis. The Veterans Administration specifies the use of Redsense, but only for high-risk patients who are receiving dialysis outside the normal treatment area.[2]

Another device for detecting VND is the WetAlert wireless wetness detector (Fresenius USA), which is integrated within the 2008K@home hemodialysis machine and uses a patch to detect wetness. The device triggers visual and audible alarms and automatically stops the blood pump and closes the venous line clamp when a blood leak is detected. WetAlert false alarms can occur when wetness from liquid other than blood is detected. Because both the WetAlert and the Redsense devices work only when blood physically interacts with a sensor, VND in which the needle is removed so quickly that blood does not touch the sensor would go undetected. Overall, blood and fluid sensing systems for VND are not widely used for hemodialysis, leaving most of the dialysis population at risk of an undetected VND. A more practical and economic solution would be to integrate detection devices into all dialysis machines that use data from the existing VP transducer to detect VND. Several patents have been filed for VND detection systems[9,11–16]; however, they have had limited or no implementation in currently available dialysis machines.

Patients receiving hemodialysis may have clinical VP parameters in which the occurrence of a VND would not trigger an alarm on the dialysis machine, and although undetected VND events are rare, the potential consequences of a VND for patients can be catastrophic. Simulations performed using a sham dialysis circuit revealed numerous clinical scenarios in which VND could go undetected by the VP alarm systems within many dialysis machines. Current dialysis machine alarm systems do not continuously compensate for upward drift in VP, which increases the pressure decrease needed to trigger a VP alarm, putting patients at risk for serious adverse events in the case of a VND. Using a VND algorithm that analyzes real-time data from a dialysis machine for the detection of VND could greatly reduce the morbidity and mortality associated with VND events while substantially reducing the stress and concerns that patients with end-stage kidney disease have regarding these rare but life-threatening events.

Disclosures

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Data Sharing Statement

All data are included in the manuscript and/or supporting information.

References

1. Gutierrez G, Reines HD, Wulf-Gutierrez ME. Clinical review: hemorrhagic shock. *Crit Care*. 2004;8(5):373–381. doi:10.1186/cc2851
2. Veterans Health Administration. *Patient Safety Advisory: Bleeding Episodes During Dialysis (AD09-02)*. Accessed October 7, 2022. https://www.patientsafety.va.gov/docs/alerts/BleedingEpisodesDuringDialysisAD09-02.pdf
3. Sandroni S, Sherockman T, Hayes-Leight K. Catastrophic hemorrhage from venous needle dislodgement during hemodialysis: continued risk of avoidable death and progress toward a solution [abstract]. *J Am Soc Nephrol*. 2008; 19(suppl l):891A.

4. Renal Physicians Association. Management solutions for Health, Inc.: appendix B: professional survey response frequencies, March 2007. In: *Health and Safety Survey to Improve Patient Safety in End Stage Renal Disease*. Renal Physicians Association, 2007.
5. Ribitsch W, Schilcher G, Hafner-Giessauf H, et al. Prevalence of detectable venous pressure drops expected with venous needle dislodgement. *Semin Dial.* 2014;27(5):507–511. doi:10.1111/sdi.12169
6. Frinak S, Zasuwa G, Dunfee T, Besarab A, Yee J. Dynamic venous access pressure ratio test for hemodialysis access monitoring. *Am J Kidney Dis.* 2002;40(4):760–768. doi:10.1053/ajkd.2002.35687
7. Corporation Temptime. Simulated blood products: 10% glycerol in water may NOT be "one size fits all; May 17, 2018. Accessed October 10, 2022. https://temptimecorp.com/2018/03/17/simulated-blood-products-10-glycerol-in-water-may-not-be-one-size-fits-all/
8. Bosart LW, Snoddy AO. Specific gravity of glycerol. *Ind Eng Chem.* 1928;20(12):1377–1379. doi:10.1021/ie50228a032
9. Frinak S, Zasuwa G, Yee J, Besarab A. Inventors; Henry Ford Health Systems, assignee: system and method of monitoring dislodgement of venous needles in dialysis patients. US patent 11,246,971 (B2). February 15, 2022.
10. Ahlmén J, Gydell KH, Hadimeri H, Hernandez I, Rogland B, Strömbom U. A new safety device for hemodialysis. *Hemodial Int.* 2008;12(2):264–267. doi:10.1111/j.1542-4758.2008.00263.x
11. Furmanski M, Roslund A, Olde B, Solem K. Inventors; Lundia G, assignee. Method and devices for monitoring flow circuits. US patent 8,718,957 (B2). May 6, 2014.
12. Wolff H, Ritter KU. Inventors: Apparatus and method for detecting venous needle dislodgement. US patent 2015/0246171 (A1). September 3, 2015.
13. Bennison C, Inventor; Baxter International Inc., Baxter Healthcare SA, Assignees: Acoustic Access Disconnect Detection System. US patent 2009/0082676 (A1). March 26, 2009.
14. Perkins LE. Inventor, Perkins LE, Vol 22. US patent; 2006/0130591:2006. Corban Enterprises, assignees: venous needle dislodgement sensor (A1)June.
15. Funkhouser C. Inventor, Baxter International Inc. Baxter Healthcare SA, assignees: system for detection of access disconnection. European patent EP3393546 (B1). January;15:2020.
16. Rohde JB. Inventor, Baxter International Inc., Baxter Healthcare SA, assignees: access disconnect detection using glucose. European patent EP2195046 (B1). August 24, 2011.

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