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Occlusion Reduction and Heparin Elimination Trial Using an Antireflux Device on Peripheral and Central Venous Catheters

ABSTRACT

Catheter occlusion and thrombosis are common problems associated with central venous catheters, peripherally inserted central catheters, and peripheral intravenous catheters. A prospective study was performed at a community hospital to determine whether an antireflux valve device would reduce the frequency of complications in these catheters and safely allow the elimination of heparin flushes for central venous catheters and peripherally inserted central catheters. The study compared complications with current intravenous practice to complication rates for the antireflux valve device. The study used evidence obtained during this trial to institute the best clinical practice.

Central venous catheters (CVCs), peripherally inserted central catheters (PICCs), and peripheral intravenous (IV) catheters are widely used in the hospital setting and are essential for the delivery of IV fluids and medications and for hemodynamic monitoring. Common problems associated with these catheters include occlusion, thrombosis, refluxed blood, phlebitis, and infiltration. Nurses and healthcare workers are challenged daily to maintain the patency of peripheral and central catheters. They often attempt to salvage the current IV or discontinue it and then start a new one, which takes valuable nursing time and increases supply costs.

Wide variations in clinical practice exist on the maintenance of IVs.[1] Multiple studies since 1989 support the use of saline flushes instead of heparin flushes for maintenance of peripheral IV catheters.[2,3] Traditionally, CVCs and PICCs have been maintained with standard protocols using an anticoagulant (heparin) that prevents clot formation and improves patency of the catheter. Positive-pressure IV devices were introduced more recently for use on central catheters and PICCs. Positive-pressure valves have resulted in decreased occlusions and led to an elimination of heparin in flushing procedures due to the design of the valve.[4]

Recent observational reports describe an increase in bloodstream infections associated with the advent of these positive-pressure valves. One report notes an increase in catheter-related bloodstream infections after switching to a luer-activated mechanical valve (MV) with positive-pressure device from a standard luer-access MV.[5] In addition, Rupp et al[6] describe an association between primary bloodstream infections and the type of needleless connector valve used. That facility changed from a split-septum device to a positive-displacement MV and noted an increase in infections per 1000 catheter days when the positive-pressure valve was used (10.64 infections compared with baseline of 2.79 infections).

Doctors Hospital, a 200-bed community hospital in Columbus, Ohio, and a part of the OhioHealth System, used a luer-activated MV (CLAVE Needle Free Connector; CLAVE®, ICU Medical Inc, San Clemente, California) but had problems with catheter occlusions, refluxed blood, and loss of catheters. In addition, heparin flushes were still required for CVC and PICC

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TABLE 1

Central Statistics: Project Month/ Anticoagulant Cross-Tabulation

Project Month	Anticoagulant: No Anticoagulant Used	Anticoagulant: Anticoagulant Used	Total
No device (August)			
Count	60	0	60
% Within project month	100	0	100
NEXUS TKO (September)			
Count	66	0	66
% Within project month	100	0	100
NEXUS TKO No Heparin (October)			
Count	22	42	64
% Within project month	34.4	65.6	100
Total			
Count	148	42	190
% Within project month	77.9	22.1	100

TABLE 2

Central Statistics: Project Month/Degree of Occlusion Cross-Tabulation

Project Month	None	Partial (Sluggish) Occlusion	Complete Occlusion or Clot	Dislodgment	Total
No device (August)					
Count	41	15	3	0	59
% Within project month	69.5	25.4	5.1	0	100
NEXUS TKO (September)					
Count	60	5	0	1	66
% Within project month	90.9	7.6	0	1.5	100
NEXUS TKO No Heparin (October)					
Count	55	3	5	1	64
% Within project month	85.9	4.7	7.8	1.6	100
Total					
Count	156	23	8	2	189
% Within project month	82.5	12.2	4.2	1.1	100

maintenance. In an effort to improve patient care, safety, and satisfaction, and to decrease the nursing time associated with malfunctioning IVs and central catheters, an antireflux pressure-activated valve device was evaluated through a nursing research trial. In addition, with the risk of heparin-induced thrombocytopenia, elimination of heparin flushes was a specific goal.[7]

METHODS

A 3-month prospective observational study was conducted in the fall of 2006 after approval from the institutional review board. The institutional review board did not require an informed consent because the device was FDA-approved and all patients would receive the same IV device. A convenience sample of patients 18 years and older with a peripheral IV catheter, central catheter (triple-lumen, subclavian, or internal jugular), or PICC (nontunnelled, open-ended) on a medical/surgical floor or intensive care unit was included in the study.

At the time of the study, the standard of care for maintenance of peripheral IV catheters included checking the IV site for complications every 2 hours and changing the site every 72 hours or more frequently if occluded or malfunctioning. Saline locks were used to maintain an IV that did not have fluid flowing through it and were flushed each shift with saline (every 12 hours). The standard of practice for CVCs and PICCs was to flush with heparin, 100 U/mL (3-5 mL per port), every shift (every 12 hours). The flushing standard was based on *Infusion Nursing Standards of Practice*, Standard 50, for central catheters

and PICCs, which recommends twice the catheter volume for flushing. If the CVC was clotted, the nurse could attempt to declot the catheter with alteplase (a thrombolytic agent). Current practice also includes the use of the luer-activated MV (CLAVE®) on all peripheral IV catheters, CVCs, and PICCs.

The antireflux device (NEXUS TKO, Nexus Medical, LLC, Lenexa, Kansas) used in the trial has a specially designed 3-position silicone antireflux valve. The valve is normally closed and opens when IV fluids are flowing. As soon as the IV fluids stop flowing from the IV bag, the valve closes and prevents blood from the patient's vascular system from entering or refluxing into the IV catheter. The valve also opens in the reverse direction for aspiration. The antireflux device is FDA approved and is being used in other hospitals in the United States as well as in the military.[8]

STUDY DESIGN

The first month consisted of tracking the rate of complications in peripheral IV catheters, CVCs, and PICCs, using our current equipment; the second month included actual usage of the antireflux device; and the third month included elimination of heparin in CVCs and PICCs and a switch to saline flushes. The 3-month study timeline follows.

Month 1

The study collected data on the rate of complications using a luer-access MV injection cap and 10-mL normal saline flush, followed by 5 mL of 100 U of heparin every 12 hours for CVCs and PICCs (per INS standard). The MV was changed 3 times a week per hospital protocol.

Month 2

The study collected data on the rate and type of complications occurring while the antireflux device was attached to the MV. The same practice protocols as those for month 1 were used, except that the MV and the antireflux device were changed once a week instead of 3 times a week.

Month 3

The study eliminated heparin flushes while using an antireflux device attached to the MV and instituted 10-mL normal saline flushes. Data were collected on

TABLE 3

Peripheral Statistics: Project Month/Number of Days for IV Cross-Tabulation

	No. of Days for Intravenous Administration					
Project Month	1 Day	2 Days	3 Days	New Admit	Did Not Indicate	Total
No device (August)						
Count	28	13	21	12	12	86
% Within project month	32.6	15.1	24.4	14	14	100
NEXUS TKO (September)						
Count	9	8	22	7	5	51
% Within project month	17.6	15.7	43.1	13.7	9.8	100
NEXUS TKO (October)						
Count	12	13	26	0	0	51
% Within project month	23.5	25.5	51	0	0	100
Total						
Count	49	34	69	19	17	188
% Within project month	26.1	18.1	36.7	10.1	9.0	100

TABLE 4

Peripheral Statistics: Project Month/Degree of Occlusion Cross-Tabulation

Project Month	Degree of Occlusion				Total
	None	Complete Occlusion or Clot	Dislodgment	Complications	
No device (August)					
Count	36	7	7	36	86
% Within project month	41.9	8.1	8.1	41.9	100
NEXUS TKO (September)					
Count	29	1	3	18	51
% Within project month	56.9	2.0	5.9	35.3	100
NEXUS TKO (October)					
Count	20	5	4	22	51
% Within project month	39.2	9.8	7.8	43.1	100
Total					
Count	85	13	14	76	188
% Within project month	45.2	6.9	7.4	40.4	100

rate and type of complications, and the MV and antireflux device were changed once per week. Complications tracked during the 3-month study included the type of occlusion (partial or complete) and the action taken, such as the use of alteplase to declot the catheter or catheter replacement. Partial occlusions were defined as an inability to withdraw blood (fibrin tail or sheath present), whereas complete occlusions were defined as an inability to infuse or withdraw blood. The study also identified patients on systemic anticoagulation therapy.

Education

Because the antireflux device was a new product to Doctors Hospital, the hospital instituted training for all shifts with visual demonstrations, posters, and daily rounds to ensure understanding of the device and the study. Training included how to

- place patients into the study and identify patients eligible for study,
- use the device and troubleshoot,
- monitor patients during treatment,
- complete tracking forms, and
- request help with problems or issues.

DATA COLLECTION

Nurses completed a tracking form on patients with the IV, PICC, or CVC. Only nurses who had completed

TABLE 5

96-Hour Addendum Trial[a]

June 2007	191 total IV catheters	55 discharged prior to 96 h	58% or 45% survived 96 h	9 phlebitis, only 1 at 96 h
July 2007	221 total IV catheters	132 discharged prior to 96 h	51% or 61% survived at least 96 h	7 phlebitis, 3 at 96 h

[a] *Rates remained 4% after the 96-hour implementation.*

National Institutes of Health research training and had submitted certificates were able to complete the tracking form. A removable label containing the patient's name and medical number was placed on the bottom half of the tracking form to identify patients entered into the study and to prevent any duplication of forms. One of the principal investigators removed the label once the form was complete and before performing any analysis.

Statistical Analysis

A *t*-test analysis evaluated the effectiveness of the antireflux device in comparison to current practice.

RESULTS

The study included 189 patients with CVCs and PICCs. Results showed a decrease in occlusion rates in catheters with the antireflux device. Occlusion rates (partial and complete combined) decreased from 30% (18 of 59) during the first month to 7.6% (5 of 66) during the second month, and finally to 12.5% (8 of 64) during month 3 when heparin flushes were eliminated (Tables 1 and 2). When comparing the degree of occlusion between pre– and post–anti-reflux valve use, a statistical significance was noted with a P value of $<.01$ as determined via a 2-tailed t test.

Initially, 188 patients were included in the peripheral IV study. Peripheral catheters showed little change in occlusion rates and complications between months 1 and 3 (Table 3). However, there was an increase in the number of days the IV lasted. During the first month when only the MV device was used, 24% of peripheral sites lasted 3 days. During month 3, when the antireflux device was used, 51% of the peripheral sites lasted 3 days (Table 4). Phlebitis rates for peripheral IVs showed a decrease when the antireflux device was used. Initial phlebitis rates were 10% (7 of 69) in the first month, whereas in month 2, they decreased to 6% (3 of 50), and in month 3, the rates dropped to 4% (2 of 55) (Table 5).

Because of these findings on peripheral IVs, the study was expanded to determine the feasibility of increasing IV site and administration set changes to 96 hours from 72 hours while maintaining a low phlebitis rate. The expanded study took place over a 2-month period in June and July 2007. During the first month of the expanded study, IV sites were changed every 96 hours, and during the second month, both IV sites and administration sets were changed every 96 hours instead of the standard 72 hours. A 2-month total of 412 IVs were monitored, with an average phlebitis rate of 3.8%: 9 of 191 for a 4.7% phlebitis rate in June and 7 of 221 for a 3.1% phlebitis rate in July (Figure 1). Grade 4 phlebitis was not noted during this 2-month period (Figure 2).

DISCUSSION

CVCs and PICCs

Use of the antireflux device resulted in a statistically significant decrease in occlusion rates in PICCs and CVCs. In addition, elimination of heparin flushes was determined to be a safe alternative. The study noted a slight increase in complete occlusions during month 3, but it was still a significant decrease as compared to overall rates of occlusion during month 1. Results of this study led to modified flushing protocols and a change in nursing policy to support saline flushes in this community hospital. Uncontrolled variables occurring during the study period included census fluctuations, with a lower census in month 1 as compared with that in months 2 and 3.

Another variable noted is that 65.6% of total study patients were already on systemic oral or subcutaneous anticoagulants. In addition, the hospital switched from 5-mL prefilled saline syringes to 3-mL and 10-mL prefilled syringes during month 3 of the study period, which may have altered flushing practice.

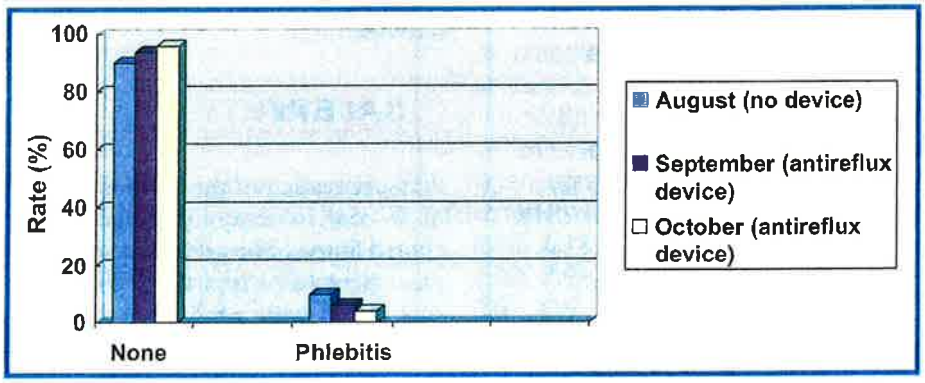

Figure 1 Rates of phlebitis.

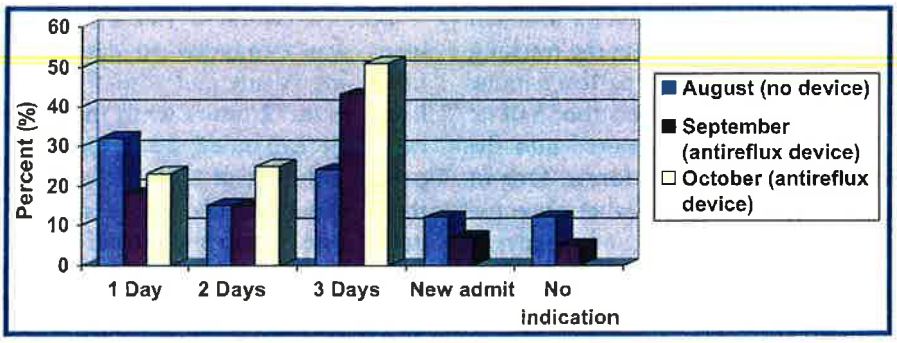

Figure 2 Peripheral IV catheters.

PERIPHERAL IV CATHETERS

Use of the antireflux valve demonstrated an increased length of duration in peripheral IV catheters. An additional benefit of the antireflux device was the documented decrease in phlebitis rates that led to an extended trial to determine the feasibility of changing from a 72-hour to a 96-hour IV site and administration set policy. Results of the 96-hour trial demonstrated a phlebitis rate less than 5% and led to the subsequent adoption of a nursing policy for 96-hour IV site and administration set changes. Use of a phlebitis scale to document the grade of phlebitis was instrumental in providing detailed nursing documentation.[9] The phlebitis scale used is shown in Figure 3.

Uncontrolled variables occurring during the study period included patient census fluctuations, with a lower census in month 1 as compared with that in months 2 and 3. Another variable was an interruption in the availability of the antireflux device for approximately 3 days during the 96-hour study portion, due to a hospital supply-chain services delivery problem. In addition, due to a standardization project that affected the entire hospital system, the cap studied during the 2-month, 96-hour trial was a positive displacement MV (SmartSite Plus® Valve, Alaris® Medical Systems, Cardinal Health, Dublin, Ohio) attached to the antireflux valve.

Grade 1: Erythema with/without pain
Grade 2: Pain at site with erythema and/or edema
Grade 3: Pain at site with erythema and/or edema, streak formation, palpable venous cord
Grade 4: Pain at site with erythema and/or edema, streak formation, palpable venous cord >1 in, purulent drainage

Grade of Phlebitis	Frequency	Percent
Grade 1	5	31.3
Grade 2	10	62.5
Grade 3	1	6.3
Grade 4	0	0

Figure 3 Phlebitis Scale. Adapted from Infusion Nurses Society.[10]

COST IMPACT

The elimination of heparin flushes resulted in cost savings as well as improved patient safety. A decrease in supplies owing to catheters lasting longer and the switch to changing caps once per week (previously 3 times per week) also affected cost savings. Opportunities for cost savings were also realized by 2 other hospitals in the OhioHealth System once they adopted antireflux technology. Before receiving final approval to bring the device into the hospital, the study had to demonstrate a cost-neutral impact to administration. The study demonstrated a 25% decrease in IV restart supplies (exact cost not available due to contractual obligations), which exceeded the original estimates of a 20% supply decrease to obtain cost-neutral status. At this time, the hospital has maintained similar cost with better technology for inpatients. However, the hospital has noted increased costs in outpatient and emergency department settings when the antireflux device is used. A suggestion for future device use is to use the device on an inpatient population only, due to savings lost on short-term patients in outpatient and emergency department settings.

SAFETY

Pressure testing of the various IV caps is critical because of the rise in computed tomography procedures in the United States. The antireflux device and the positive displacement MV (SmartSite® Plus Valve) have been pressure tested with a fail mode of 425 psi. The other MV used (CLAVE®, ICU Medical Inc, San Clemente, California) has also been pressure tested to 300 psi. All 3 caps mentioned above have been effective for the

hospital's current pressure-testing computed tomography studies. In addition, as studies of arterial flow require increasing rates for injection, pressure-rated caps will become a necessity.

INFECTION

Although recent literature has noted an increase in bloodstream infections associated with needleless devices, Doctors Hospital has had no increase in infections with the use of the displacement MV and antireflux device. Its use will require continued monitoring and continued education to remind staff to scrub the cap properly prior to connection.

LIMITATIONS/FUTURE STUDIES

Limitations of this study include the single geographical site, short study time, and the uncontrolled variables mentioned above. Potential future studies should include studies on dialysis catheters, larger populations, and determination of how the device improves phlebitis rates.

RECOMMENDATIONS

Overall, this device improved patient care and safety by decreasing phlebitis rates, increasing catheter longevity, and decreasing the use of heparin and alteplase. It is best suited for an inpatient environment in which the decreased use of supplies and medications will neutralize the cost impact.

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