

Clinical Evaluation of a Positive Pressure Device to Prevent Central Venous Catheter Occlusion: Results of a Pilot Study

Margaret A. Rummel, RN, MHA, OCN®, Patrick J. Donnelly, RN, MS, CCRN,
and Cathy C. Fortenbaugh, RN, MSN, AOCN®

The presence of a central venous catheter (CVC) is a known risk factor for thrombus formation. Catheter-related thrombus (CRT) may be intraluminal or extraluminal and can cause partial or total catheter occlusion. CVC occlusions impair IV fluid and medication administration, blood sampling, and blood product administration. Possible complications of CRT formation include septicemia, superior vena cava syndrome, venous thrombosis, and pulmonary embolism (Bona, 1999; Smith, 1998).

The incidence of CRT reportedly ranges from 20%–55%; however, varying definitions of “occlusion” are used in the literature, and no standardized method for determining the degree of occlusion exists (Cobos, Dixon, & Keung, 1998; Lowell & Bothe, 1995; Whitman, 1996). In a prospective study, DeCicco et al. (1997) found that 63 of 95 patients (66%) without symptoms of CVC occlusion had evidence of catheter thrombus formation when venograms were performed. Although CRT is diagnosed in many patients with CVCs, many more may be asymptomatic yet have CRT.

One of the complications related to central venous catheters is occlusion secondary to thrombus formation within or surrounding the catheter lumen. Historically, methods to prevent these occlusions have included vigorous flushing, coordinated flushing-clamping techniques, and antithrombotic prophylaxis using low-dose warfarin or low molecular weight heparin. Positive displacement devices recently have become available that prevent retrograde blood flow and consequently reduce the risk of thrombus formation in the catheter lumen. Maintaining catheter patency results in fewer treatment delays and diagnostic procedures, decreased use of thrombolytics, lower costs, and increased patient satisfaction. A trial of a positive displacement device was conducted on an inpatient oncology unit to determine its effectiveness in preventing catheter occlusions. The easy-to-use device effectively reduced the number of occlusions and resulted in significant cost savings when compared to thrombolytic therapy.

Pathogenesis of Thrombus Formation

Several factors appear to predispose patients to CRT. Catheter characteristics are believed to play a major role; polyethylene, polyvinyl chloride, and teflon catheters are associated with a higher incidence of CRT than silicone catheters. Double-lumen catheters are more prone to CRT than single

lumen, and prolonged indwelling times also are factors in CRT development. Patients with solid tumors, hypercoagulable states, coexisting infection, mechanical factors (e.g., mediastinal tumors), and those receiving infusate with a low pH or high osmolarity are at risk for CRT (Bona, 1999; Hadaway, 1998; Raad et al., 1994). Catheters that are inadequately maintained (e.g., not flushed or inadequately flushed after use, not regularly flushed when not in use) are prone to thrombus formation and occlusion.

Another risk factor associated with CRT is negative displacement of blood that backflows into the catheter lumen when an infusion device, such as a syringe, is

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removed from an injection port attached to the CVC. This retrograde blood flow into the catheter lumen may result in stasis of blood in the catheter and subsequent intraluminal thrombus formation (see Figure 1).

Prevention of Catheter-Related Thrombus

Although much has been written about managing catheter occlusions, prevention of CRT has received less attention. Methods used in clinical practice to help prevent thrombus formation include several untested methods, such as vigorous flushing with 10–20 ml of normal saline, coordinated flushing/clamping techniques, and the pulsatile flow technique (Camp-Sorrell, 1996; Doyle & Nale, 1999; Krzywda, 1999). The goal of these approaches is to clear the catheter and prevent negative displacement of blood. However, forward flushing while withdrawing a saline-filled syringe works best with a needle attached to the syringe and is very difficult when leur-lock devices are used. Leur-lock and other needleless devices are being used increasingly to reduce needle-stick injuries among healthcare workers.

Prophylactic low-dose warfarin also has been used to reduce CRT. At one institution, the rate of CRT was 11% for patients who received warfarin compared to 21% in patients who were not anticoagulated (Carr & Rabinowitz, 2000). In a study of patients with

hematological malignancies, 5 out of 108 (5%) patients who received low-dose warfarin (1 mg/day) developed CRT at a median of day 72 from the time of insertion. Fifteen of 115 patients (13%) not anticoagulated developed CRT at a median of day 16 (Boraks et al., 1998). Another study of patients with hematologic and solid tumors found that thrombotic events, mainly CRT, occurred in 10 out of 55 patients (18%), including 7 who received low-dose warfarin. Bleeding occurred in three patients, all on warfarin (Ratcliffe, Broadfoot, Davidson, Kelly, & Greaves, 1999). The effectiveness of low molecular weight heparin in preventing CRT was evaluated in a group of patients with implanted ports. Thirty-one of 145 patients (21%) developed CRT, and the incidence of CRT was higher in patients with peripherally implanted ports compared to those with centrally implanted ports (Tesselaar, Ouwkerk, Rosendaal, & Osanto, 2001).

All of the various CRT prevention measures described above require nursing time, incur supply, and medication costs; some (e.g., anticoagulation) require patient adherence to medication regimens and place patients at risk for bleeding or other complications.

Positive Pressure Devices

A CVC device that creates positive pressure and prevents backflow of blood into the catheter may be useful in preventing intralu-

minal or extraluminal thrombus formation (Macklin, 2000). Positive displacement refers to the volume of infusate that exits the catheter lumen when an infusion device, such as a syringe, is removed from the injection port (see Figure 2). Eliminating blood in the CVC lumen prevents the stasis of blood in the catheter and may help to prevent CRT. Two brands of positive pressure devices are marketed in the United States: CLC2000™ (ICU Medical, Inc., San Clemente, CA) and B-D Posiflow™ IV Access System (Becton Dickinson, Franklin Lakes, NJ).

Pilot Study

The staff on the inpatient oncology unit at Pennsylvania Hospital, part of the University of Pennsylvania Health System, conducted a pilot study to evaluate the CLC2000 device. The T-shaped positive pressure device contains an O-ring that positively displaces blood whenever a syringe or IV tubing is disconnected (see Figure 3). This design feature also negates the need for heparin flushes; the manufacturer recommends flushing with normal saline only (ICU Medical, 2001). It is latex-free, lipid and blood compatible, and can be used with central, peripheral, and arterial lines (ICU Medical). The device is designed to be used as a component of a needless system; if a needle is used, either intentionally or inadvertently, the O-ring mechanism will begin to leak. The device then needs to be changed at once because its positive displacement ability now is lost.

Prior to initiating the pilot study, the nursing staff gathered data on the oncology unit's catheter occlusion rate. Staff members then conducted a research utilization project that resulted in the development of an evidence-based policy and procedure for thrombolytic instillation to restore patency in occluded CVC catheters. The nurses developing the policy noted that little evidence-based information existed in the literature addressing CRT prevention and, therefore, designed the pilot study to assess a positive displacement device.

The CLC2000 positive displacement device was used on all patients with a CVC on the 42-bed inpatient oncology unit. Approximately 10 inpatients per day were entered into the six-week study, for a total of 420 catheter lumens. Seven hundred positive displacement devices were used during the study period. The control group consisted of approximately 500 outpatients with catheter lumens who received usual care and had conventional injection caps on their CVCs; the positive displacement device was not used in these patients. The number in the outpatient group fluctuated slightly during the study period

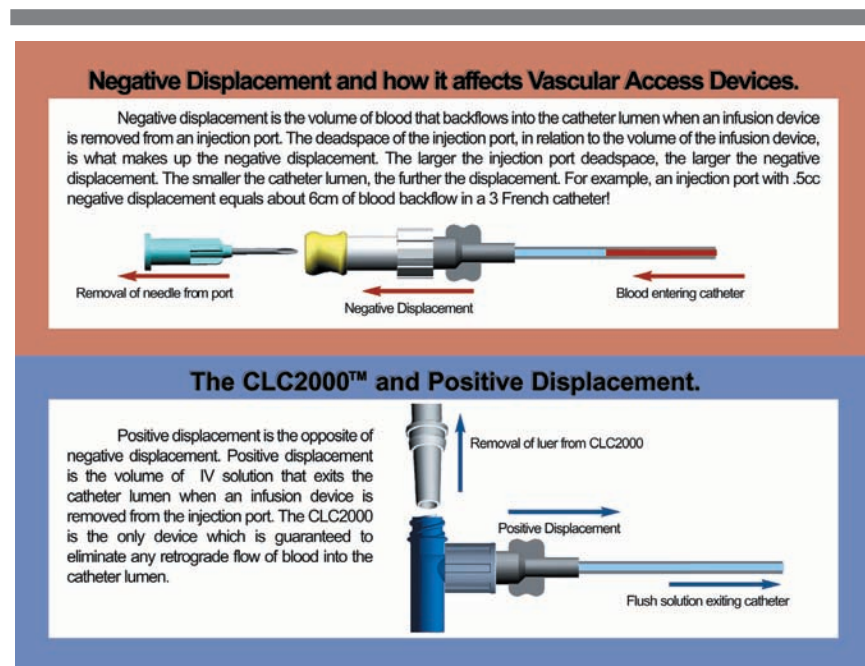


FIGURE 1. MECHANISMS INVOLVED IN NEGATIVE AND POSITIVE DISPLACEMENT OF BLOOD IN CATHETER LUMENS

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How the CLC2000™ Works

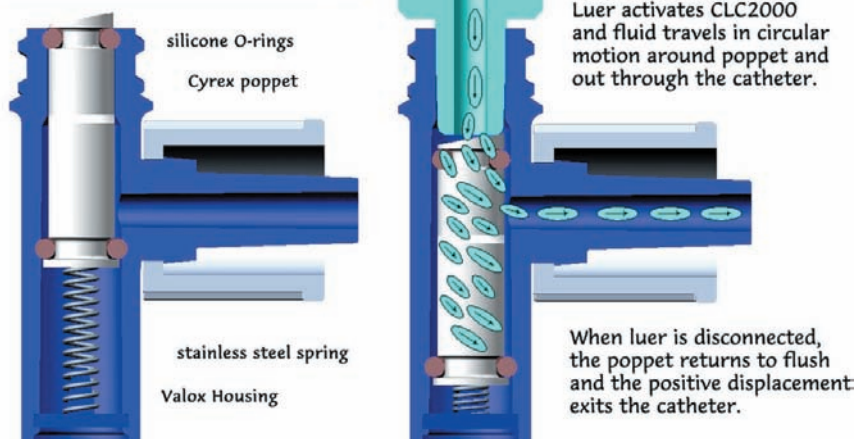


FIGURE 2. CROSS-SECTION OF THE CLC2000™ POSITIVE DISPLACEMENT DEVICE

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because a few of these patients were transferred to the oncology unit for chemotherapy or did not have conventional injection caps in place because they were receiving continuous infusion chemotherapy. The majority of patients had double-lumen peripherally inserted central catheters and single- or double-lumen implanted ports. The device also was evaluated in patients with double-lumen tunneled catheters and triple-lumen apheresis catheters. Patients received fluids, blood products, chemotherapy, antibiotics, opioids, and other IV medications via CVCs. In addition, CVCs were used for blood sampling. The manufacturer recommends that CLC2000 be changed every 24 hours or per institutional protocol (ICU Medical, 2001), and they were changed weekly when routine

CVC dressing changes were performed for those patients whose hospital stays exceeded one week. The conventional injection caps used on the outpatient group were changed at weekly intervals.

Nurses were educated on the use of the device by a representative of the manufacturer and followed the procedures for using the CLC2000 as outlined in Figures 4 and 5. “Catheter occlusion” was defined as impairment or inability to infuse fluids or medications or withdraw blood or fluid from the CVC.

During the six-week study period, one patient on the inpatient unit who did not have the device in place (by inadvertent omission) developed a fibrin sheath requiring declotting with tissue plasminogen

activator (t-PA). Eleven outpatients, who received care at home, in the clinic, or in both settings, experienced CVC occlusions and required t-PA instillation.

The total cost of 700 CLC2000 devices is \$2,065 (costing \$2.95 each). Conventional injection caps cost approximately \$1.60 each. The approximate cost of t-PA instillation at Pennsylvania Hospital is \$300. For patients with double-lumen CVCs, the cost to restore patency of the CVC is \$600 because both lumens require t-PA instillation. The costs associated with this pilot study are presented in the inset below.

Outpatient study costs amounted to approximately \$7,100, and inpatient study costs were approximately \$2,665, representing a cost difference of \$4,435. Theoretically, if all of the outpatients had the device in place and CVC occlusion was avoided in this group, a potential savings of \$5,892.90 could result (\$6,300 for t-PA instillation minus \$407.10 for CLC2000 devices, changed weekly, for 23 patients). Further cost savings possibly could have been achieved if the inpatient with the inadvertently placed conventional injection cap had a positive displacement device in place. The cost to declot this patient’s CRT was included in the inpatient cost analysis; the objective of this pilot study was to examine and compare inpatient and outpatient costs of caps and CRT declotting during the six-week study period.

The pilot study data was shared with nursing leaders at the authors’ institution. Points of discussion included the cost of routinely stocking and using the positive displacement

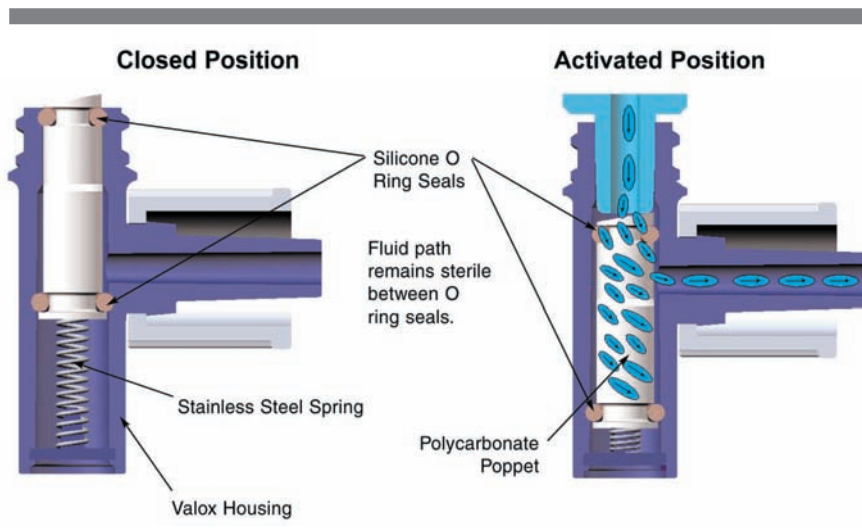


FIGURE 3. INTERNAL VIEW OF FLUID PATH FOR CLC2000™ POSITIVE DISPLACEMENT DEVICE

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Approximate Outpatient Costs for 500 Catheter Lumens (Injection Caps, Declotting Procedures)

Conventional injection caps = \$800
 Outpatients requiring tissue plasminogen activator (t-PA)
 • 11 patients with single-lumen central venous catheters (CVCs) = \$3,300
 • 5 patients with double-lumen CVCs = \$3,000
Total outpatient cost = \$7,100

Approximate Inpatient Costs for 420 Catheter Lumens (Positive Displacement Devices, Declotting Procedure)

CLC-2000™ = \$2,065
 Inpatients requiring t-PA
 • 1 patient with double-lumen CVC = \$600
Total inpatient cost = \$2,665

Cost Comparison

Approximate outpatient costs = \$7,100
 Approximate inpatient costs = \$2,665
Cost difference = \$4,435

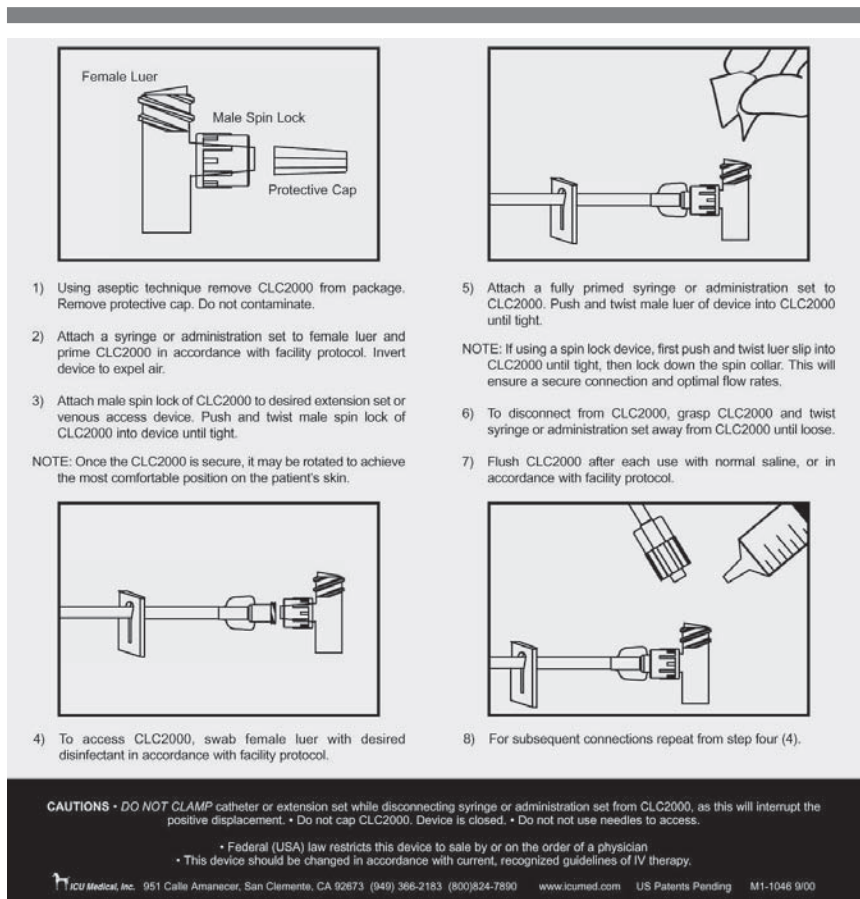


FIGURE 4. PROCEDURE FOR ATTACHING AND USING THE CLC2000™ FOR CENTRAL, PERIPHERAL, AND ARTERIAL LINES

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devices, as well as potential cost savings that could be achieved by reducing the number of fluoroscopic procedures and thrombolytic instillations and their associated costs in terms of nursing time and treatment delays. Anecdotal data from nurses indicated that they found the device easy to use and that the device was accepted well by patients.

The positive displacement device was approved by the nursing leaders for routine use, and it has been used for the past six months on all patients on the oncology unit, with no incidents of catheter occlusion occurring. In addition, the device now is used hospital-wide on patients with CVCs with the exception of areas in which a CVC is briefly used, such as the emergency room and day stay unit. The device costs approximately \$3; for short infusions, this cost outweighs the likelihood that an occlusion will occur.

The nursing staff on units in which the device is used received comprehensive initial training about using the device, and the information will be reviewed in ongoing skills fairs for nurses. Policy and procedural information on using positive displacement de-

vices was added to the institution's manuals.

One possible limitation in implementing the hospital-wide use of the positive displacement device is the potential that agency, per diem, and newly hired nurses will be unfamiliar with the device and misuse it. However, if the CVC is clamped or a needle is used with the device and positive displacement is negated, then the end result is no worse than having a "regular cap" at the end of the catheter. Another potential limitation is that patients who continue their therapy at home or in physicians' offices will need to inform their nurses about the device; another option would be to change the device to a conventional injection cap prior to discharge.

Results of this pilot study evaluating the CLC2000 cannot be generalized to other institutions or patient populations. Patients were not randomized; instead a convenience sample was used. Future research, perhaps using patients as their own controls, with randomized sampling is indicated to further evaluate the effectiveness of positive displacement devices in reducing CRT incidence.

Implications for Practice

Because CRT is a multifaceted phenomenon, not all risk factors for CRT can be eliminated. Patients with certain risk factors, such as hypercoagulable states or solid tumors, are still at risk for developing CRT even if positive displacement devices are used. However, these devices appear to prevent negative displacement of blood into the CVC lumen and, consequently, have the potential to reduce CVC occlusion incidence. Potential cost savings also may result, especially in institutions in which heparin flushes are used routinely. Converting to saline flushes reduces costs, and added cost savings may occur if using the device results in fewer CVC occlusions requiring fluoroscopic evaluation and thrombolytic therapy. The device also may play a role in promoting patient satisfaction; patients who are able to complete treatment without interruption and those who encounter fewer problems during treatment generally are more pleased with their care than patients who encounter delays and difficulties.

When positive pressure devices are used to help prevent CRT, nurses who use these devices must be knowledgeable about their proper use and able to educate patients and other colleagues (such as the patient's home-care nurse) about them. These devices have the potential to reduce CRT, but only if they are used properly.

Summary

A common complication related to CVCs is intraluminal thrombus formation and subsequent occlusion. Although various measures to reduce or prevent CRT have been used historically, few have been evaluated scientifically. The findings of this pilot study suggest that the use of a positive displacement device may reduce CRT incidence and CRT-related costs. However, more research is needed in these areas.

Author Contact: Margaret A. Rummel, RN, MHA, OCN®, can be reached at 817 Yardley, PA 19067 or at marumm@pa.hosp.com

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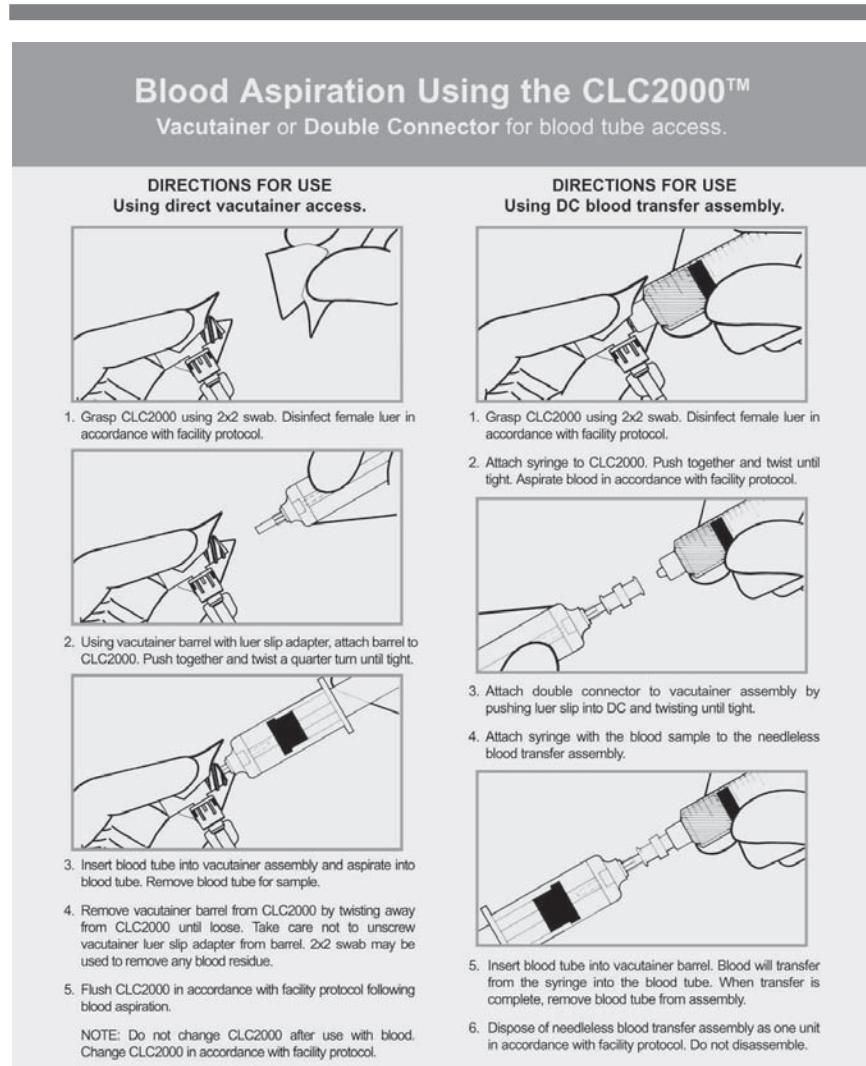


FIGURE 5. PROCEDURES FOR DRAWING BLOOD FROM CENTRAL VENOUS CATHETERS WITH CLC2000™ DEVICES IN PLACE

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Rapid Recap

Clinical Evaluation of a Positive Pressure Device to Prevent Central Venous Catheter Occlusion: Results of a Pilot Study

- Retrograde blood flow into a central venous catheter (CVC) can become a thrombus and partially or totally occlude the catheter.
- Risk factors for catheter-related thrombus formation include the presence of a solid tumor, hypercoagulable states, rigid and dual lumen catheters, prolonged dwell times, coexisting infection, and acidic infuscates.
- Positive displacement devices prevent retrograde blood flow into CVCs.
- When evaluating a new device, factors to consider include efficacy, ease of use, cost, and acceptability to patients and nurses.
- Patient and staff education and orientation to a new device are key to successfully implementing a practice change.