Femoral Artery Closure After Cardiac Catheterization

Wallace J. Hamel, RN, BSN, MSN, APRN

Coronary heart disease is the leading cause of death in the United States today. Treatment options include medical management, coronary interventions, and cardiac revascularization. An estimated 1.3 million inpatient cardiac catheterizations are performed annually; half of those patients have percutaneous cardiac interventions and about 400,000 undergo coronary artery bypass graft operations. Since the late 1990s, the death rate due to coronary heart disease has decreased by more than 30%. Because percutaneous cardiac interventions quickly reestablish blood flow to the heart, patients have a shorter length of stay and less cost.

Cardiac catheterization is the traditional method for examining coronary anatomy, determining coronary artery disease, and providing percutaneous intervention. Access to the heart is through a catheter via the femoral or radial artery. The femoral artery is preferred because of its larger diameter. Catheters range in size from 4F to 10F. Which size to use depends on the vascular and cardiac anatomy, the need to adequately opacify the coronary arteries and cardiac chambers, how much the catheter must be manipulated, and the desire to limit vascular injury and complications. Catheters from 7F to 10F are considered large. They allow increased manipulation and excellent visualization, but because of their large size, they can cause complications such as injury of the coronary or peripheral vasculature and bleeding. Because of their smaller size, catheters from 4F to 6F are less traumatic and subsequently have less chance of complications. In addition, hemostasis is easier to achieve when smaller catheters are removed. A smaller size, however, may decrease the quality of the study because of limitations in the ability to deliver contrast material. A 6F catheter is used most often because it is large enough for percutaneous intervention but small enough to allow rapid hemostasis.

PRIME POINTS

- After diagnostic and interventional cardiac catheterization, femoral artery closure devices offer quicker time to hemostasis, ambulation, and discharge than does manual compression.
- Nurses should understand how femoral artery closure devices work, the potential vascular complications that may occur with their use, and the recommended time to ambulation and discharge.

CEContinuing Education

This article has been designated for CE credit. A closed-book, multiple-choice examination follows this article, which tests your knowledge of the following objectives:

1. Identify 2 benefits resulting from percutaneous cardiac interventions quickly reestablishing blood flow to the heart
2. Describe 3 traditional things cardiac catheterization is designed to do
3. List 2 risks related to the cardiac catheterization method of arterial closure

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Complications of Cardiac Catheterization

Cardiac catheterization (even with a 6F catheter) can cause complications, both vascular access complications and complications from closure of the arteriotomy incision. Like any invasive procedure, accessing the heart through the femoral artery has risks. In 2% to 10% of cases, complications such as bleeding, thrombotic complications, and vascular trauma occur (Table 1). Procedural factors that influence risk include sheath size greater than 8F, excessive use of anticoagulants, and site of entry below the common femoral artery. Vascular complications can also be affected by any of the following patient-specific factors: history of hypertension, female sex, bleeding diathesis, peripheral vascular disease, age, obesity, and anticoagulation regimen. Additional complications can arise from closure of the arteriotomy incision. After removal of the catheter, hemostasis is traditionally achieved by manual compression. This technique, developed by Dr Sven Seldinger, a radiologist from Sweden, in the 1950s, has been the reference standard for hemostasis of the vascular access site. In order to achieve hemostasis, a significant amount of pressure over the access site is required, along with prolonged bed rest for the patient. Manual compression may cause pain for some patients and deep vein thrombosis due to femoral vein compression and stasis.

**Table 1 Complications of femoral artery access during cardiac catheterization**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Cause</th>
<th>Clinical findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessel laceration</td>
<td>Puncture or laceration of femoral artery</td>
<td>Secondary complications from bleeding: hematoma, retroperitoneal hemorrhage, pseudoaneurysm, arteriovenous fistula</td>
</tr>
<tr>
<td>Hematoma</td>
<td>Bleeding into groin or thigh</td>
<td>Hard palpable swelling at the access site. Variation in size: small, &lt;1 cm; medium, 1-5 cm; large &gt;5 cm. Pain in groin area</td>
</tr>
<tr>
<td>Retroperitoneal hemorrhage</td>
<td>Bleeding behind the serous membrane lining the walls of the abdominal and pelvic cavities</td>
<td>Hypovolemia, hypotension, decreased hematocrit that may require blood transfusion, flank pain (diagnosed by using computed tomography)</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>Commonly a puncture of one of the weaker walls of the branch of the femoral artery, causing bleeding in the tissue surrounding the artery via a small tract and forming a wall around the artery</td>
<td>Painful pulsatile mass, new bruit, groin pain or burning, swelling at groin site (confirmed by using ultrasonography)</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>Puncture of the artery and vein causing a tract to form and allowing direct communication between them</td>
<td>Usually asymptomatic, high-output congestive heart failure, palpable thrill, audible bruit (confirmed by using ultrasonography)</td>
</tr>
<tr>
<td>Acute vessel closure/thrombus</td>
<td>Embolized thrombus from catheter. Thrombus from dissection flap</td>
<td>Leg: paresthesia, pain, pallor, pulseless, cold</td>
</tr>
<tr>
<td>Neural damage</td>
<td>Femoral nerve injury during access. Retroperitoneal hematoma or pseudoaneurysm hematoma causing compression of lumbar plexus. Femoral hematoma causing nerve compression</td>
<td>Pain, tingling at groin site, numbness at site or down leg, difficulty moving leg, leg weakness, decreased patellar tendon reflex</td>
</tr>
<tr>
<td>Infection</td>
<td>Foreign body administration, compromised sterile technique, prolonged in-dwelling sheath time, hygiene</td>
<td>Pain, erythema, fever, swelling, purulent drainage at access point</td>
</tr>
</tbody>
</table>

* Based on data from Turi, Weisz, White, and Davis et al.

**Author**

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In 1994, femoral artery closure devices (FACDs) were introduced as an alternative to compression. Their purpose was to reduce time to hemostasis and ambulation. The superiority of FACDs over manual compression remains unclear. Vascular access complications remain the leading source of morbidity, cost, and legal ramifications. In this article, I examine the safety and effectiveness of 4 methods of closing arteriotomy incisions: manual compression and FACD closure with sutures, a collagen plug, and a clip. Then I describe the complications, advantages, and disadvantages of each method. Last, I address nursing care after cardiac catheterization and discharge instructions.

Safety and Effectiveness of Closure Methods

The method of arterial closure is chosen by the physician. Arterial closure can be managed by manual compression. The purpose of manual compression is to stop bleeding from the femoral artery by compressing the artery and allowing clot formation. Actual compression of the artery can be done manually or with mechanical compression devices. With mechanical devices, a stand with a compression disk like a C-clamp or a compression arch with a pneumatic dome is used to compress the artery. Although compression is relatively safe and easy to perform, achieving hemostasis by compression can be painful and can take up to a mean of 20 minutes, especially if a large catheter or anti-coagulants were used.

Arterial closure can also be accomplished with an FACD. These devices mechanically close the puncture site in the femoral artery. The suture-mediated closure device ties off the femoral artery with the use of sutures, similar to conventional surgical techniques. Another device available uses an extravascular clip rather than sutures to close off the puncture site in the artery. Another device seals the arteriotomy by using a collagen plug that stimulates thrombus formation and platelet aggregation. All 3 FACDs (suture, clip, and plug) must be deployed through a specialized carrier device. The device is introduced through the sheath put in place during the catheterization. The devices can accommodate a variety of sheath sizes and can close puncture sites up to 10F. Table 2 summarizes the effectiveness and safety of all 4 methods of arterial closure. Time to achieve hemostasis specific to each method is discussed in the sections on advantages and disadvantages.

Vascular Complications Related to Method of Arterial Closure

In addition to the vascular complications associated with accessing the femoral artery, specific complications can occur depending on the method of arterial closure (Table 3). No large randomized trials have been done to determine vascular complications specific to any device. Typically, safety data compare major

<table>
<thead>
<tr>
<th>Table 2 Safety and effectiveness of the different methods of arterial closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial closure method</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>Safety, %</td>
</tr>
<tr>
<td>Effectiveness, %</td>
</tr>
</tbody>
</table>

Safety is defined as the percentage of patients with major or minor vascular complications. Minor vascular complications are hematoma greater than 10 cm, arteriovenous fistulas, or pseudoaneurysm. Major vascular complications are death due to vascular complications, vascular repair, major vascular bleeding where hemoglobin level decreases more than 3 g/dL due to bleeding at the access site or retroperitoneal bleeding, vessel occlusion, and loss of pulse.

Effectiveness is defined as the percentage of patients in whom the device was deployed successfully and the femoral artery was closed.

<table>
<thead>
<tr>
<th>Table 3 Device-specific complications</th>
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</thead>
<tbody>
<tr>
<td>Device/manufacturer</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Compression</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Perclose Proglide</td>
</tr>
<tr>
<td>Abbott Vascular Devices Redwood City, California</td>
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<tr>
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<tr>
<td>Angio-Seal</td>
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<tr>
<td>St Jude Medical</td>
</tr>
<tr>
<td>St Paul, Minnesota</td>
</tr>
<tr>
<td>Starclose</td>
</tr>
<tr>
<td>Abbott Vascular Devices Redwood City, California</td>
</tr>
</tbody>
</table>

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and minor vascular complications, as described earlier. One complication that all 3 FACDs have in common is failure of the device, which occurs in up to 8% of cases.\textsuperscript{12} When failure occurs, manual compression is used.

Selection of Closure Method: Preventing Complications at the Vascular Site

In an effort to avoid complications, a femoral angiogram is recommended to rule out marked peripheral vascular disease, extensive calcification, or plaque and to aid in proper sheath placement in the common femoral artery.\textsuperscript{10,14,19} The results of the femoral angiogram, examination of the patient for such features as size and anticoagulant use, and procedural risk factors help physicians decide which method to use to close the arteriotomy incision. Table 4 displays the indications for use of compression vs an FACD.

The Closure Devices

Suture-Mediated Closure System

The Perclose system, introduced in 1994, was the first suture-mediated device to be approved by the Food and Drug Administration. Abbott Vascular Devices in Redwood City, California, manufactures and distributes these suture-mediated devices: Prostar XL, Perclose A-T, and Perclose ProGlide. The Perclose ProGlide is the latest generation, introduced in 2004. It offers improvements in the ease of knot delivery and strength and the noninflammatory nature of the suture material.\textsuperscript{13}

The Perclose ProGlide allows percutaneous delivery of a suture to close the access site to the common femoral artery during either diagnostic or interventional catheterization procedures with 5F to 8F sheaths.\textsuperscript{21} The system is composed of a sheath, a guide, a knot pusher accessory, and a suture trimmer. Inside the guide are needles, sutures, and the foot.\textsuperscript{19} The guide is advanced through the sheath into the femoral artery and precisely controls the placement of needles around the puncture site with the help of the foot.\textsuperscript{21} The needles are deployed to capture the sutures (Figure 1). The plunger holding the needles is retracted, and the knot is advanced by using a knot pusher. The Perclose ProGlide is completely removed from the artery, and the knot is tightened. Hemostasis is achieved when the knot is fully advanced to the arterial surface. Last, the tails of the sutures are trimmed below the surface of the skin. A dry, sterile dressing is applied at the insertion point.\textsuperscript{21}

Collagen Plug Closure System

The Angio-Seal vascular closure device is manufactured and marketed by St Jude Medical, Incorporated, in St Paul, Minnesota. The models available include Angio-Seal VIP

\begin{table}[h]
\centering
\caption{Indications for different methods of femoral artery closure}
\begin{tabular}{|l|l|}
\hline
Method & Indication \\
\hline
Manual compression & Arteriotomy site is below the femoral bifurcation\textsuperscript{10}  \\
& Common femoral artery is less than 5 mm in diameter\textsuperscript{10}  \\
& Extensive plaque or calcification is present in the common femoral artery\textsuperscript{20}  \\
& Extensive scar tissue is present at the access site\textsuperscript{10}  \\
& Patient is obese  \\
& Patient is on an anticoagulation regimen  \\
\hline
Devices & Femoral puncture entry point in the common femoral artery, 1 or 2 cm above the femoral bifurcation\textsuperscript{21}  \\
& Patient has undergone many procedures and has extensive fibrosis around the artery\textsuperscript{20}  \\
& Artery is very calcified (collagen plug)\textsuperscript{20}  \\
& Vessel is free from excessive calcium and severe fibrosis (suture-mediated closure)\textsuperscript{20}  \\
\hline
\end{tabular}
\end{table}

\textbf{Table 4} Indications for different methods of femoral artery closure

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Perclose ProGlide Suture-Mediated Closure System: needle deployment. Reprinted from Perclose ProGlide Suture-Mediated Closure System,\textsuperscript{21} with permission.}
\end{figure}
Platform, Angio-Seal STS Plus Platform, and Angio-Seal STS Platform. The main difference among them is the range in size of the anchor that holds the collagen plug in place in the arteriotomy incision.

The Angio-Seal device is made up of 3 components: a specially designed polymer anchor, an absorbable collagen sponge, and an absorbable self-tightening suture. All 3 components dissolve in 60 to 90 days. The sponge is positioned in the puncture track outside the artery wall by a pulley system created by the anchor and suture. The device seals and sandwiches the arteriotomy between the anchor and the collagen plug. The collagen not only acts as a plug at the puncture site but has coagulation-inducing properties that aid in hemostasis (Figure 2).22

Clip Closure System
The StarClose is a clip-mediated closure device developed by Abbott Vascular in Redwood City, California. It was approved by the Food and Drug Administration in 2005 but has been successfully used in Europe since 2004. In January 2007, StarClose was approved for interventional use. The StarClose introduces a small, circumferential, flexible clip that mechanically binds the surface of the femoral artery together (Figure 3). The clip is made of nitinol, a nickel-titanium alloy whose superelastic properties allow it to return to its

![Figure 2](image-url) *Angio-Seal vascular closure device.* Reprinted from Angio-Seal [instructions for use]; used with permission.

![Figure 3](image-url) *Use of the StarClose: (A) application of the clip. (B) Hemostasis of the femoral artery. (C) Hemostasis with StarClose device in place.* From StarClose Vascular Closure System; reprinted with permission.
original shape once released from the device. Its use involves a 4-step or click process: (1) replacement of the procedural sheath with the Star-Close sheath, (2) deployment of the vessel locator, (3) delivery of the clip, and (4) deployment of the clip, achieving hemostasis. Because the clip is on the outside of the artery, nothing is left behind on the inside to cause potential blockages later.

Advantages and Disadvantages of Closure Methods

The various methods of femoral artery closure have numerous advantages and disadvantages (Table 5). A reduction in time to hemostasis and ambulation is an important advantage of using any of the FACDs compared with compression. Other advantages include a reduction in work load for cardiac catheterization staff, an increase in patients’ comfort, a decrease in patients’ length of stay, and the subsequent cost savings. The cost savings is reduced somewhat by the initial cost for a closure device and supplies compared with the costs of manual compression. No one device is considered superior to another. A variety of variables must be considered for safe and effective closure of the femoral artery such as patient and procedural factors and the physician’s ability in deploying the device.

Nursing Care After Cardiac Catheterization

The nursing standards of care for patients undergoing an interventional cardiac catheterization are not well established. The main goals of management after the procedure are the maintenance of hemostasis at the puncture site and assessment for vascular complications. Meeting these goals requires effective assessment of patients before the procedure, knowledge of exactly how hemostasis of the arteriotomy incision was achieved, and diligent monitoring of vital signs, groin site, and pulses (Table 6). Oozing at the groin site may be controlled by 10 minutes of manual pressure, mechanical compression, or a pressure dressing. Duration of bed rest and time to ambulation depend on the method of arterial closure. The criteria for determining whether a patient is ready for ambulation and discharge are that the overall clinical condition of the patient (including vital signs)
has returned to baseline levels, sedation has worn off, and hemostasis at the groin site has been maintained. The final decision for time to ambulation and discharge is up to the cardiac interventionalist.

**Discharge Instructions**

Before a patient leaves the hospital, discharge instructions (Table 7) should be reviewed with the patient and the patient’s family. The information should be presented at a level they understand.

**Conclusion**

Methods of femoral artery closure after cardiac catheterization include compression, suture, collagen plug, and clip closure. A variety of factors can influence the choice of which method to use, including the physician’s preference, ability to successfully deploy the device, cost, and patient-specific factors such as peripheral vascular disease and use of anticoagulation. No one method is better than the others. Although all 4 methods are comparable in terms of safety and effectiveness, the FACDs consistently are associated with quicker hemostasis and ambulation. Information on vascular complications from access of the femoral artery, the methods of arterial closure, and postprocedural care including discharge instructions helps critical care nurses provide safe and effective care to patients after cardiac catheterization.

### Table 6 Checklist for prevention of vascular access complications after cardiac catheterization

<table>
<thead>
<tr>
<th>Assessment of patient before procedure (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age________</td>
</tr>
<tr>
<td>Sex_______</td>
</tr>
<tr>
<td>Anticoagulant use______________</td>
</tr>
<tr>
<td>Coagulopathy</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Hypertension</td>
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<tr>
<td>Obesity</td>
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<tr>
<td>Peripheral vascular disease</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure-related factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter size used_______</td>
</tr>
<tr>
<td>Method of arterial closure________</td>
</tr>
<tr>
<td>Successful device deployment______</td>
</tr>
<tr>
<td>Vascular complications during access____________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nursing interventions after the procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile, clean dressing intact</td>
</tr>
<tr>
<td>Monitoring: every 15 min x 4 Blood pressure every 30 min x 2 Heart rate every 60 min x 2 Distal pulses Access site Oxygen saturation</td>
</tr>
</tbody>
</table>

- Hypotension
- Hematoma development
- Loss of distal pulses
- Limb ischemia
- Signs and symptoms of infection (fever, drainage, and excessive pain)

- Analgesic used________

- Bed rest until _______ AM/PM (6 hours after hemostasis achieved with compression)
- May be discharged________AM/PM

* Based on data from Weisz,6 StarClose Vascular Closure System,19 Cardiac Cath Lab Post PCI Orders,28 and Clinical Policy: AngioSeal Hemostatic Puncture Closure Device.29

### Table 7 Discharge instructions after cardiac catheterization

1. Do not strain or lift anything greater than 10 lb (22.4 kg) for 2 to 3 days.
2. Do not drive or operate any dangerous machinery for 24 hours.
3. Keep the dressing on, clean, and dry for 24 hours.
4. After 24 hours, the dressing may be removed and a shower is allowed.
5. Clean the area with mild soap and water and then cover it with a bandage.
6. Once the skin has healed, bathing in a tub or swimming is allowed.
7. Inspect the groin site daily and report to the physician any bleeding at the site that cannot be controlled with manual pressure for 10 minutes, unusual pain at the access site or affected extremity, unusual swelling at the access site, or signs or symptoms of infection such as redness, pain, or fever.

* Based on data from Clinical Policy: AngioSeal Hemostatic Puncture Closure Device,19 Cardiac Instructions: Cardiac Cath/PTCA,30 and Tremko.31

Financial Disclosures
None reported.

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References
**Learning objectives:**
1. Identify 2 benefits resulting from percutaneous cardiac interventions quickly restoring blood flow to the heart
2. Describe 3 traditional things cardiac catheterization is designed to do
3. List 2 risks related to the cardiac catheterization method of arterial closure

---

1. What size of cardiac catheterization catheters allows increased manipulation and excellent visualization but can result in complications including injury to coronary and peripheral vasculature and bleeding?
   - a. 4F to 10F
   - b. 7F to 10F
   - c. 7F to 12F
   - d. 4F to 6F

2. What size of cardiac catheterization catheter is used most often because it is large enough for percutaneous intervention but small enough to allow rapid hemostasis?
   - a. 6F
   - b. 4F
   - c. 7F
   - d. 10F

3. How often do complications such as bleeding, thrombotic complications, and vascular trauma occur in cardiac catheterizations?
   - a. 5% to 10%
   - b. 10% to 25%
   - c. 2% to 25%
   - d. 2% to 10%

4. Who developed a technique to achieve hemostasis by manual compression after removal of the cardiac catheter?
   - a. Alexander Swan
   - b. Sven Seldinger
   - c. Marion Ganz
   - d. William Arrow

5. When were femoral closure devices introduced as an alternative to compression to reduce time until hemostasis and ambulation?
   - a. 1994
   - b. 1996
   - c. 1998
   - d. 1997

6. What is the leading source of morbidity, cost, and legal ramifications after cardiac catheterization?
   - a. Cardiac insult
   - b. Vascular complications
   - c. Hematoma
   - d. Hemodynamic instability

---

7. Which of the following is correct regarding hemostasis by compression after cardiac catheter removal?
   - a. It is difficult to achieve and takes up to a mean of 20 minutes.
   - b. It is painful but quick to achieve depending on the catheter size.
   - c. It is ineffective if incorrectly applied.
   - d. It is painful and can take up to a mean of 20 minutes.

8. Which of the following complications do all 3 femoral artery closure devices have in common?
   - a. Hematomas 8% of the time
   - b. Failure 8% of the time
   - c. Vascular 8% of the time
   - d. Inappropriate for 8% of patients

9. Which of the following procedures is recommended to avoid complications at the vascular site?
   - a. Femoral angiogram
   - b. Ultrasound of the femoral artery
   - c. Lower abdominal radiograph
   - d. Coagulation studies

10. In what year was the Perclose system the first suture-mediated device approved by the Food and Drug Administration introduced?
   - a. 1994
   - b. 1996
   - c. 1995
   - d. 1997

11. Which of the following are the goals after cardiac catheterization?
   - a. Early ambulation and hemostasis
   - b. Hemostasis and assessment for vascular complications
   - c. Assessment for vascular complications and cardiac compromise
   - d. Early ambulation and assessment for cardiac compromise

12. Which of the following methods of closure is associated with quicker hemostasis and ambulation?
   - a. Clip closure
   - b. Manual closing
   - c. Collagen plug
   - d. Femoral artery closure devices

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**Program evaluation**

<table>
<thead>
<tr>
<th>Objective 1 was met</th>
<th>Objective 2 was met</th>
<th>Objective 3 was met</th>
<th>Content was relevant to my nursing practice</th>
<th>Method of CE is effective for this content</th>
<th>The level of difficulty of this test was: easy, medium, difficult</th>
<th>To complete this program, it took me _______ hours/minutes.</th>
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<td>□ Yes</td>
<td>□ Yes</td>
<td>□ Yes</td>
<td>□ Yes</td>
<td>□ Easy</td>
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</table>

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Crit Care Nurse 2009;29 39-46 10.4037/ccn2009157
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