APPENDIX 10-10

Patient Guide Proposed – Perclose ProStyle

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Catheterization

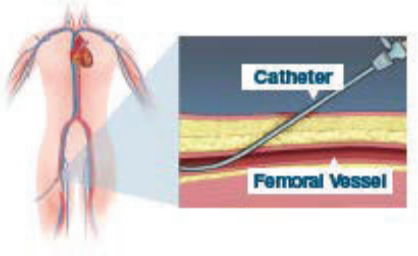
Catheterization is a procedure commonly used to evaluate or treat certain types of disease in vessels of the heart and other parts of the body.

During the procedure:

- The doctor makes an opening in the femoral vessel (a large blood vessel in the leg) and inserts a flexible tube called a catheter.
- The catheter is used either to observe the condition of the coronary or peripheral blood vessels or to treat blockages that interfere with the normal flow of blood through these blood vessels, or to repair and / or assist structures within the heart or great vessels so they can resume normal function.
- After the procedure is completed, the doctor removes the catheter and closes the femoral access site (the opening in the femoral vessel).

Suture-Mediated Closure and Repair

Your doctor has chosen to use a procedure called Suture-Mediated Closure and Repair (SMCR) to close your access site after catheterization. With SMCR, a device is used to deliver one or two surgical stitches to the femoral vessel to reliably stop bleeding.



Alternative Treatments

Before SMCR was available, doctors closed the access site by applying direct pressure (manual compression) using their hands for fifteen minutes to one hour or more to allow a blood clot to form in the opening of the femoral vessel. Because movement could dislodge the clot and cause the blood vessel to bleed, patients had to remain immobile for four to eight hours or more after compression was completed.

Alternative methods for closing the access site following catheterization include mechanical compression, other vessel closure devices, and surgical closure.

Benefits and Risks

Vascular closure devices provide an alternative to manual compression. These devices provide sealing of the femoral access site, so there is less need for prolonged compression.

Potential benefits using the Perclose™ ProStyle™ SMCR System include:

- Decreased amount of time required for you to lie flat after your procedure. You may be able to get out of bed sooner than compared with manual compression.
- You may be discharged earlier.
- The risk of immediate bleeding from the groin puncture site may be reduced.
- Patient comfort may be increased compared with manual compression (firm compression applied to the bleeding area).

Potential risks associated with the Perclose ProStyle SMCR System:

- Allergic reactions to device materials
- Vessel complications which can occur in the vessels used to access the structures of the heart. These complications may require blood transfusion or surgical repair, including:
    - Bleeding
    - Low number of red blood cells which can cause tiredness and shortness of breath.
    - Bruising or hematoma – a collection of leaked blood outside a blood vessel
    - Bleeding in the space behind the abdomen
    - Formation of an abnormal connection between an artery and the vein next to it
    - Weakness in the wall of an artery / localized abnormal dilatation of a blood vessel
    - A blood vessel abnormality resembling an aneurysm (localized abnormal dilatation of a blood vessel) but consisting of a collection of blood with persistent flow outside an artery, contained by surrounding tissue and due to a leaking hole through all layers of the arterial wall. The leaking hold is due to injury of (e.g. rupture of or trauma to) the arterial wall, and is related to the vessel puncture site.
    - Partial or complete tear or separation of the inner wall of a blood vessel
    - Hole or tear in a blood vessel
    - Unintended movement of air, tissue, plaque, blood clot, or device material downstream in a vessel resulting in blockage in blood flow
    - A localized physical condition in which part of the body becomes swollen, reddened, warm, and often painful, especially as a reaction to injury or infection.
    - Opening of a wound
    - Scar formation
- Irregular heartbeats (caused by abnormal electrical activity in the heart from upper to lower heart chambers)
- Femoral artery / venous complications which may require additional intervention, including:

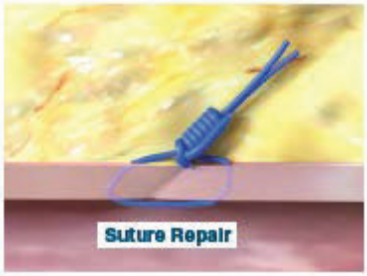
  - Narrowing of blood vessels / Blood vessel spasm (both of which may cause blockage of blood flow)
  - Formation of an abnormal connection between an artery and the vein next to it
  - Partial or complete tear or separation of the inner wall of a blood vessel
  - Decreased blood supply to the legs which may cause cramping or pain
  - Nerve damage caused by compression of the nerves, injury to the nerve or interruption of blood supply to the nerves
  - Numbness
  - Formation or presence of a blood clot inside a blood vessel
  - Damage to a blood vessel
- Blood clot in the vein which may result in pain, swelling, and/or skin redness, or clots traveling in the blood stream and lodging in the lung (with the possibility of resultant difficulty in breathing)
- Infection – local or widespread
- Pain
- Low blood pressure / High blood pressure
- Death
- The failure of a device to work properly or function as intended

What to Expect During the Procedure

Prior to the procedure, your doctor will administer a local anesthetic to reduce discomfort. When the SMCR device is inserted, you will feel some pressure that usually lasts only a few seconds. As the needles and stitches pass through the vessel wall, you may feel some momentary discomfort. After the access site is closed, a small dressing will be applied to the opening in the skin. Your doctor may need to also provide compression (using her / his hands) if SMCR is unable to fully close the access site.

After the Procedure

After the procedure, your heart rate, blood pressure, and pulse will be monitored and the access site will be checked regularly for bleeding. In most cases, you will be able to sit up in bed soon after the procedure, and depending on the catheterization procedure and medications you are receiving, your doctor may allow you to get up to use the bathroom. Some oozing of blood from the access site may occur, especially if you have received blood thinners. The nursing staff may apply compression to control any oozing after the procedure.



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Activity
Resume normal activity after two days, letting pain be your guide. Example: Driving, heavy lifting, straining.

Wound Care
Gently clean the groin area using soap and water from a standing position in the shower. Dry thoroughly and apply clean dry dressing to the area. Do not bathe or swim for 5 days or until the wound is completely closed.

Please Call the Physician if:

- Significant bleeding at the groin site. (Bleeding uncontrolled after 10 minutes of firm compression.)
- Increased swelling to the groin area.
- Unusual pain in the access site or leg.
- Signs of infection: non-healing wound, redness, pain or swelling at site, fever or chills.

CONTENT: SIDE 2 OF PATIENT GUIDE

Going Home

Your doctor will talk to you about limitations in your activities and care of the access site. The following instructions will guide you on how to care for the site, as well as provide other helpful information.

Care of Your Incision

- You may shower 24 hours after the procedure. Remove the bandage before showering. If Steri-Strips‡ (thin strips of tape across the incision) are in place, allow them to remain in place until they fall off on their own.
- Gently clean the site daily using soap and water while standing in the shower. Dry thoroughly.

Abbott **IMPLANT CARD**

Perclose™ ProStyle™
Suture-Mediated Closure and Repair System

Patient Name: _____

Date: _____

Physician: _____

Telephone: _____

Access Site: ☐ Right Groin ☐ Left Groin

SMCR (Suture-Mediated Closure and Repair) is a procedure which prevents bleeding from the groin immediately following catheterization procedures. The SMCR devices place one or two surgical stitches in the femoral vessel to reliably stop bleeding.

Normal Observations

- Mild oozing from the incision site.
- Possible bruising to the groin area.
- Formation of a small lump in the groin area which may last up to 6 weeks.

- You may apply an antibacterial ointment (e.g., Neosporin‡). Otherwise, cleaning the site with soap and water should be sufficient. Do not apply powders or lotions.
- Cover the site with a bandage or dressing that covers the entire area. A square adhesive bandage seals well.
- Keep the site clean and dry to prevent infection. If the bandage becomes wet, remove it and replace it with a new one.
- Do not sit in a bathtub or pool of water for 5 days or until the wound has completely healed.
- Inspect the site daily.

Activity

- You may resume normal activity in 2 days, including driving, letting pain be your guide.
- Limit lifting over 10 pounds for one week or until the wound heals.

Normal Observations

- Soreness or tenderness that may last one week.
- Mild oozing from the incision site.
- Possible bruising that could last 2 weeks.
- Formation of a small lump (1.5 to 2.5 cm), which may last up to 6 weeks.

Call the Doctor Immediately if You Experience Any of the Following:

- Significant bleeding.
- Increased swelling of groin or leg.
- Unusual pain at groin or down that leg.
- Signs of infection: redness, warmth to touch, drainage (other than a little blood on the bandage), poorly healing incision, fever or chills.

CLINICAL STUDIES

The CLOSER Study

The CLOSER trial tested the safety and effectiveness of a device similar to the Perclose ProGlide™ Suture-Mediated Closure (SMC) device[1] to close small holes in the femoral artery. A small hole of the femoral artery is opened during procedures that require a catheter (long, thin hollow tube) and possibly other medical devices to be inserted into the artery. The device was tested in two groups based on how doctors used the device during the procedure.

In group 1 (post-close group), doctors used the device only at the end of the procedure. There were 225 patients in group 1 of the study.

In group 2 (pre-close group), doctors used the device at the beginning and end of the procedure. There were 160 patients in group 2 of the study.

The study looked at the time it took for patients to leave the hospital after the procedure (time to hospital discharge). For the post-close group, the time to hospital discharge was 29 hours and for the pre-close group the time to hospital discharge was 30 hours. After 30 days from the procedure, the post-close group and the pre-close group both had two patients with major complications.

The PEVAR Clinical Study

The PEVAR study tested the safety and effectiveness of the Perclose ProGlide SMC System[2] compared to surgery (surgical cutdown) to close large holes in femoral arteries. A large hole in the femoral artery is opened during an invasive procedure, requiring a catheter and / or possibly other medical devices to be inserted into the artery. At 30 days after the procedure, the major access site vascular complications on the same side where the femoral artery hole was created was 6% for Perclose ProGlide and 10% for surgery. Perclose ProGlide was not found to have worse outcomes with respect to major complications than surgery.

[1] Perclose ProStyle SMCR System and Perclose ProGlide SMC System are design evolutions of the Closer 6F SMC System. The results of the CLOSER clinical study are applicable to the Perclose ProStyle SMCR and Perclose ProGlide SMC Systems because of the similarity of the devices.

[2] Perclose ProStyle SMCR System is a design evolution of the Perclose ProGlide SMC System. The results of the PEVAR and REALISM clinical studies are applicable to the Perclose ProStyle SMCR System because of the similarity of the devices.

The Perclose ProGlide Venous Analysis

The Perclose ProGlide SMC device[2] was evaluated using data from the EVEREST II/REALISM study, which was a study designed to collect data on the Abbott Vascular MitraClip™ System. The MitraClip System is used to repair a valve in the heart (the mitral valve) by placing a clip on the leaflets of the valve. A doctor puts the MitraClip device in the heart using a catheter that is passed through a large hole in the femoral vein (a large vessel in your leg). Some patients in the EVEREST II/ REALISM study were treated with the Perclose ProGlide device to close the hole in the femoral vein after the MitraClip was put in the heart.

During the EVEREST II/REALISM study, 159 patients were treated using Perclose ProGlide. From the time of the procedure through 30 days after the procedure, 98% of the 159 patients did not experience any major complications at the location on the leg where Perclose ProGlide was used. Additionally, from the time of the procedure through 30 days after the procedure, 94% of the 159 patients did not experience any minor complications at the location on the leg where Perclose ProGlide was used. The findings support that Perclose ProGlide is safe and effective in closure of the large holes of the femoral vein.

The Perclose SMC Multiple Access Sites in Single Vein Analysis

The Perclose SMC device was evaluated using data from 3 real-world studies – the Santa Barbara Cottage Hospital (SBCH) Study, the Emory School of Medicine (ESM) Study and the VAscular Closure for Cardiac Ablation Registry (VACCAR) Study. Each of these studies was designed to collect data in patients undergoing closure of multiple holes of the femoral vein during cardiac ablation procedures.

The SBCH study treated 519 patients with Perclose SMC. From the time of procedure through 30 days after the procedure, 99% of the 519 patients did not experience any major complications at the location on the leg where Perclose SMC was used.

The ESM study treated 53 patients with Perclose SMC with a 99% success rate. From the time of procedure through 30 days after the procedure, 96% of the 53 patients did not experience any major complications at the location on the leg where Perclose SMC was used.

The VACCAR study treated 75 patients with Perclose SMC. During the hospital stay none of the 75 patients experienced any major complications at the location on the

leg where Perclose SMC was used.

The findings support that Perclose SMC is safe and effective in closure of multiple large holes of the femoral vein.

The Perclose SMC Multi-Access DUS Trial Analysis

The Perclose SMC device was evaluated for safety and efficacy in closure of multiple holes of the femoral vein by using a duplex ultrasound (DUS).
The study treated 36 patients with Perclose SMC. No major complications were found in all the 36 patients at discharge. A DUS performed in asymptomatic patients at discharge did not find any major complications. Additionally, a DUS performed at 30 days after discharge also did not find any major complications in all 36 patients. The findings support that Perclose SMC can be safely used to close multiple large holes of the femoral vein.

CONTENT: SIDE 2 OF PATIENT GUIDE (Front Panel of Folded Patient Guide)

Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

PATIENT INFORMATION GUIDE

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