After Your Procedure

What You Need to Know About Closure of Your Access Site

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

ALTERNATIVE TREATMENTS
Before SMC 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 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 ProGlide SMC 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 to manual compression.
- You may be discharged home 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 ProGlide SMC System:
- Allergic reaction or hypersensitivity to device components
- Low number of red blood cells due to bleeding, causing tiredness and shortness of breath
- Narrowing of the arteries
- Formation of an abnormal connection between artery and the vein next to it
- Bleeding / hemorrhage
- Bruising / blood clot
- Death
- Blood clots in vein
- Device entrapment
- Device failure / malfunction / misplacement
- Diminished pulse to the legs
- Movement of air, tissue, plaque, blood clot, or device material resulting in blockage of blood flow
• Low or high blood pressure
• Condition that occurs in response to an infection that causes widespread inflammation, resulting in poor blood supply to vital organs
• Swelling, redness and pain at the access site
• Partial or complete tear of the wall of the 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
• Pain
• Hole / tear
• Leaking of blood from the vessel to the surrounding tissue (usually as a result of a puncture to the vessel)
• A blood clot that causes a sudden blockage in a lung blood vessel, usually due to a blood clot that traveled to the lung from the leg
• Bleeding in the abdomen
• Formation or presence of a blood clot inside a blood vessel
• Complications at the groin access site
• Sudden drop in blood pressure that may cause fainting
• Narrowing of blood vessels due to spasm of vessel walls
• Partial or complete wound separation

WHAT TO EXPECT DURING THE PROCEDURE
Prior to the procedure, your doctor will administer a local anesthetic to reduce discomfort. When the SMC 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 artery 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 SMC 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.

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 site daily using soap and water while standing in the shower. Dry thoroughly.
- 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 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 wound heals.

Normal Observations

- Soreness or tenderness that may last one week.
- Mild ooze from 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 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 device 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 Suture-Mediated Closure System 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 (long, thin hollow tube) 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.

The ProGlide Venous Analysis

The ProGlide Suture Mediated Closure device 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 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 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 the 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 the ProGlide was used. The findings support that ProGlide is safe and effective in closure of the large holes of the femoral vein.

SUTURE MEDIATED CLOSURE DISCHARGE CARD

Patient Name:
Date:
Physician:
Telephone:
Access Site: __________Right Groin __________Left Groin

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

Normal Observations
• Mild oozing of blood from the incision site.
• Possible bruising to groin area.
• Formation of small lump in groin area which may last up to 6 weeks.

SUTURE MEDIATED CLOSURE DISCHARGE CARD

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 area. Do not bathe or swim for 5 days or until the wound is completely closed.

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

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