Procedures/Risks:central venous catheter

Central Venous Catheter Placement

Procedure: Placement of the central venous catheter will take place in the Interventional Radiology Department (IRD) at The Ohio State University. The procedure will be explained to you in detail by the radiologist or nurse practitioner at the IRD, who will do the procedure. You may be asked by the radiologist to sign a separate consent form to show that you agree to have the procedure done. This visit will take about six hours. Except in rare cases, this visit will not require an overnight stay in the hospital.

Before the central venous catheter is placed your vital signs will be checked and your current medications will be reviewed. Placement of a central venous catheter involves the following:

The radiologist uses ultrasound to see if the vein at the base of your neck is suitable (easily identified). Before the procedure, an intravenous (IV) catheter is placed in a vein in your arm to give IV antibiotics to prevent infection. An IV catheter is a very thin flexible plastic tube that is inserted into a vein using a needle. We may give you medication before the procedure to help you relax. The area where the IV will be inserted is cleaned thoroughly with an antiseptic solution and sterile cloths are placed over the area to lower the risk of infection. A local anesthetic is injected to numb the area.

Once the area is numb, the radiologist makes a small cut in the skin. A needle is then inserted through the small cut in the skin and placed in the vein at the base of the neck. The radiologist creates a tunnel under the skin from the upper chest to the neck incision. The catheter is passed through the tunnel and into the jugular vein. The tip of the catheter is placed in the main vein of the chest. The radiologist uses ultrasound to guide and check the placement of the catheter. In some cases, the radiologist may also use a type of X-ray, called "fluoroscopy" to guide the catheter placement as well. As part of the catheter placement, you may also be given medications, including antibiotics.

One or two stitches are used to close the small cut at the base of the neck and a stitch is also used around the catheter on the outside to hold it in place. The catheter will exit the skin in the upper chest, and will look something like an IV.

A Dacron-fiber cuff is placed below the skin to hold the catheter in place and to prevent infection. Over time, body fluids cause the cuff to expand and tissue forms in and around it to hold it in place.

Following the placement procedure, an x-ray is done to check the catheter placement. You will stay in the Interventional Radiology suite for about two hours after the procedure is completed to make sure that you are doing well and that there are no problems.

Central Venous Catheter Removal

Procedure: When you have stopped taking the [study medication] permanently, the catheter will be removed. The catheter may also need to be removed if it becomes infected or stops working correctly. The catheter will be removed by a doctor or Nurse Practitioner.

Catheter Removal Process:

- An antiseptic will be put on your skin around the catheter site to clean germs from the skin.
- An injection of medication to numb the area at and around the exit site will be given. This will produce some discomfort from the needle prick and a temporary burning feeling when the medication is given. The area will become numb within a minute or two.
- The doctor will then separate the skin and other tissue near the exit site from the catheter. This is the area under the skin that has grown into the cuff holding the catheter in place.
- Rarely, a small incision may need to be made in the skin to allow the doctor to better reach this cuff. The sensation of releasing the tissue will produce a feeling of pressure.
- When the catheter is released from the skin, the doctor will pull back the catheter until it is removed.
- Pressure will be put on the neck area where the catheter entered the vein. This will be held in place for several minutes to prevent bleeding under the skin. The doctor may put a suture or "stitch" at the exit site opening or, if an incision was made, to the incision.
- As needed, medications may be given (including antibiotics), or additional procedures performed, as part of the catheter removal.

Risks: The risks of the central venous catheter include:

- Infection of skin, near the exit site of the catheter or along the catheter tube
- Infection in the blood—this can sometimes cause infection of the heart or other parts of the body, which can be very serious. This may require the catheter to be removed.
- Blood clot in the vein or the catheter tube
- Blood clot in the lung
- Puncture of an artery during line placement
- Collapse of the lung
- Breakage or accidental removal of the catheter

You will be given instructions and written information on catheter care *to prevent potential problems and to recognize catheter problems early*. For any questions or concerns you will be able to be in contact with the researchers 24 hours a day, 7 days a week.

The catheter *must be* <u>cared for daily</u> to keep it working correctly. If properly cared for, the catheter is designed to last indefinitely. Some serious problems could, however, require that

it be removed. Other less serious problems may develop which can be handled with the catheter remaining in place. If you have an infection or other problem with the catheter, the catheter may have to be replaced one or more times during the study. This involves a surgical procedure to remove the original catheter and a repeat of the catheter placement procedure to implant a new catheter. If the catheter never becomes infected and there are no other problems with the catheter, it is possible that the catheter may remain in place for two years or more.

Some risks are more likely to occur during different time periods that the catheter will be in place.

Early problems (during or in the weeks following catheter placement) include:

- There will be some discomfort at the surgical incision site until it heals.
- Puncture of an artery (a hole made in an artery) during placement of the catheter. Problems of puncture are usually local, in the area immediately around the puncture site; however, there is the potential for serious bleeding to occur. This risk is minimized with the use of an ultrasound to guide placement of the central venous catheter.
- During the placement procedure air may get into the lung space, causing the lung to partially or completely collapse. A lung collapse may result in being admitted to the hospital, and may result in serious complications, including death.
- Infection of the wound where the catheter comes out of the chest. This type of infection may be controlled with oral or intravenous antibiotics. Admission to a hospital may be necessary if the infection is serious.

The following potential risks can occur more often the longer the catheter is in place include:

INFECTION

Long term placement of catheters can be complicated by the development of a local infection at the site of catheter entry. This can present with redness, fever, or pain. An infection can occur along the blood vessel. Both of these types of infection can be associated with an infection of the bloodstream. This can cause fever, chills, a drop in blood pressure, overwhelming infection known as sepsis, and in some cases can infect the heart. In serious cases this can lead to death.

At the first sign of infection of the catheter or catheter site, blood cultures are obtained and appropriate antibiotics are begun. In most cases, the catheter will need to be removed. It can be replaced when the infection has been properly treated. If you have the symptoms of one of these infections, you will be referred to an infectious disease doctor for evaluation.

BLOOD CLOTS

Blood clots can occur during use of a central line. While this problem can be fixed using a medication to dissolve the clot, the risk of developing another clot increases after developing the first one.

The use of medication to dissolve the clot also increases the risk of bleeding during this clearing procedure. Blood clots inside the catheter can extend into the vein and cause a blood clot in the vein or break off to cause a blood clot in the lung or other organs. Blood clots left untreated can cause serious or life-threatening problems, and can lead to death.

If blood clots develop in the vein or go to the lung, the catheter will be removed to decrease the risk of new ones developing. You may need to take medications that thin the blood for several months. Swelling of the arm, neck or face that can result from a blood clot in the vein may continue for several months or even longer.

CATHETER BREAKS

Though the catheter is designed to last indefinitely, cracks or breaks in the catheter may occur as the catheter ages. Most often, this occurs in the tubing that extends outside the body. This is a more common problem and repair kits can permanently fix it. However, with a break in the catheter there is an increased risk of an infection developing inside the catheter. There is also the rare potential for the air to get in the blood. If large amounts of air get into the blood stream it is an emergency that requires hospitalization.

The catheter extends outside the chest by about 12 inches. While this may be accepted for some, it may cause negative feelings for others. Once the wound heals, it is safe to do most normal activities of daily living. Sports activity is permitted except for contact sports where there is a risk of the catheter being pulled out. Showering is may be permitted, once the incision is healed and inspected by the researchers. The dressing site should be covered with plastic and securely fastened around the edges with tape to prevent the dressing from getting wet. If the dressing does get wet, it should be changed. *The catheter should not be placed underwater* (taking a tub bath, hot tub, etc). Swimming is *not* permitted.

Risks related to Catheter Placement and Removal include:

- Infection
- Feeling faint
- Bleeding or bruising in the area of the exit site or where the catheter was under your skin
- Discomfort
- Allergic reaction to the numbing medication or skin antiseptic
- Inability to remove the catheter without the addition of a new skin incision
- Air getting into the chest cavity causing a partial or complete collapse of a lung

•	Breakage of the catheter resulting in part of the catheter remaining in the body or blood stream.