

PARASTERNAL MEDIASTINOTOMY WITH BIOPSY (CHAMBERLAIN PROCEDURE)

You have decided to have an important procedure and we appreciate your selection of UCLA Healthcare to meet your needs. It is important to you and to us that you fully understand the risks, benefits and alternatives to the procedure you have planned. The purpose of this document is to provide written information regarding the risks, benefits and alternatives to this procedure. The information provided here is a supplement to the discussions you have had with your surgeon(s) in preparation for the procedure. You should read this material and ask your surgeon(s) any questions you have before giving your consent.

The Procedure: You have a condition that requires open visualization (mediastinotomy) and possible sampling (biopsy) of certain structures in the center portion of your chest (mediastinum). This is performed in the evaluation of cancers, infections, and other respiratory diseases. During the procedure, a small 1 inch incision is made just beside your breastbone and a tunnel is made into your chest. Your lung is gently pushed to the side and the structures and organs in the center portion of your chest are visualize and biopsied as necessary. In some cases, a rigid tube with a light and video camera (mediastinoscope) is used to aid in the process. Your surgeon(s) will obtain one or more biopsies, which is done with a miniature device specifically made to take a small sample from the desired tissues. This is particularly useful in diseases involving the left lung. In certain situations, the space around the lung can also be inspected and biopsied if appropriate. The procedure can last from 15 minutes to as long as 1-2 hours, depending on the individual patient’s circumstances. The procedure requires general anesthesia and is frequently performed as an outpatient procedure.

Benefits

Some benefits that may be gained from undergoing mediastinotomy are listed below. Your physician cannot guarantee you will receive any of these benefits. Only you can decide if the benefits are worth the associated risk(s).

1. Mediastinotomy with biopsies may yield important information about

- established and/or new (unsuspected) diseases involving your lungs and/or chest which might not be detected by any other test(s) and/or x-ray(s).
- 2. Mediastinotomy with biopsies may establish a diagnosis, which could substantially change your future treatment and prognosis.

3. Mediastinotomy with biopsy, in unusual cases, may improve airflow into and out of the lungs by removing large fluid collections or masses that

compress the airway and lung, thereby resulting in better breathing following the procedure.

Risks

Before undergoing this procedure, a thorough understanding of the associated risks is essential. The following risks are well recognized, but there may be other risks not included in this list that are unforeseen by your surgeon(s):

1. **Bleeding** in the chest may occur during or following the procedure. The chance of bleeding increases if multiple biopsies are performed. Although any bleeding that may occur usually amounts to only a few ounces (30-90 cc) of blood; in rare circumstances, bleeding can become significant and life-threatening, requiring your surgeon(s) to make a large incision through your breastbone (median sternotomy) to stop the bleeding. Occasionally, a small amount of bleeding after the procedure along with swelling causes a lump to form under the incision. This slowly disappears a few days or up to a few weeks following the procedure. Bleeding is made worse by taking aspirin, certain anti-inflammatory medications (NSAID's, ie, Advil, Aleve, Vioxx, etc.), and blood thinners (ie, coumadin, heparin, etc.). Generally, these medications should be stopped for a week prior to the procedure. If you are taking any of these medications, please inform your physician.
2. If you have a bleeding problem, have been on blood thinners (anticoagulants), or have an anemia (low red blood cell count), it may be

necessary in rare cases to give you a **blood transfusion**. If you require blood transfusion and have not arranged to have your own blood stored ahead of time and available for the procedure, the use of blood from designated or anonymous donors could be necessary. If you receive this type of blood, you could develop fevers (1 in 100), an allergic reaction (1 in 100), red blood cell destruction or "hemolytic reaction" (1 in 6000), hepatitis B (1 in 50,000), hepatitis C (1 in 100,000), human immunodeficiency viral infection or "HIV" (1 in 500,000), other blood-borne infection, ie., syphilis, malaria, Chagas' disease, other viruses, etc. (1 in 1000), or a severe/fatal acute or allergic reaction (1 in 100,000).

3. **Infections** may develop following mediastinotomy. Possible infections include an infection in the incision, an infection of the major airways (bronchitis) an infection of the space around the lung (empyema) and an infection of the lung itself (pneumonia). Infections at insertion sites of intravenous catheters (i.v.'s) also occur. These infections usually are accompanied by fevers and either a cough productive of yellowish or green phlegm or pain, redness, and possibly drainage at the incision or at the site of a intravenous catheter. The treatment of these infections is antibiotics with or without expectorants. Additionally, empyemas are drained with tubes

placed between the ribs into the chest space. With treatment essentially all infections can be cured.

4. **Hoarseness** may occur following the procedure and is normally due to irritation from the breathing tube used for anesthesia. This lasts only a few days. Very infrequently, the nerves going to your vocal cords, which run along side the airway can get stretched and damaged leading to more significant hoarseness. Again, in most instances, this is only temporary, lasting up to several weeks. Only rarely is nerve damage permanent. If this occurs, your hoarseness can almost always be improved with vocal cord injections or implants, which involves a procedure performed by head and neck surgeons.
5. **Breathing difficulty** with or without a low blood oxygen level may develop during or following mediastinotomy. This does not occur very frequently but is more likely if you have a pre-existing breathing problem, ie., asthma, emphysema, "COPD", etc. You could experience wheezing and/or chest tightness. During the procedure you will be given additional oxygen to breathe, and in simple cases, medications to help your breathing may be administered. If you develop serious breathing difficulty, however, it may become necessary to place a breathing (endotracheal) tube into your airway to assist your breathing. This could require hospital admission and the use of a mechanical ventilator.
6. **Paralysis of the diaphragm**, which is the large muscle at the bottom of your chest that aids in breathing, may lead to shortness of breath. This can occur

if the nerve that is responsible for its function and that runs along the side of the mediastinum is damaged during the procedure. Unless you have significant lung disease, the shortness of breath usually only occurs with maximum exercise and not with normal activities. Most often the changes are permanent.

7. **Abnormal heart beats** (arrhythmias) can occur during almost any procedure done on the chest but are rare during mediastinotomy. You are more likely to develop arrhythmias if you have had one previously or have significant heart problems. If they do occur, you may experience palpitations and could require medication to stop or control the abnormal heart beats. Most arrhythmias that occur are easily treated, are temporary (lasting only minutes to hours), and are not necessarily an indication of a serious underlying heart problem. In rare circumstances, arrhythmias can lead to low blood pressure requiring the brief application of an amount of electrical energy to the heart (cardioversion) to stop it. If you have severe heart disease, a heart attack or stroke also could occur during or immediately following the procedure, although this is rare.
8. **Leakage of air from the lung** or from the mediastinoscope into the sack surrounding the lung with collapse of the lung (pneumothorax) occurs occasionally during or shortly following the procedure. Many people have no symptoms and the pneumothorax is detected only by an x-ray, but some patients develop mild to severe shortness of breath, particularly if

there is a pre-existing lung problem. A small pneumothorax can be observed and may need no treatment, but larger pneumothoraces and those associated with shortness of breath require a small tube to be placed through the skin into the chest to remove the air. This sometimes requires a hospital admission.

9. **Medication reactions** occur only rarely during or following mediastinotomy. The medications commonly used are widely available and include lidocaine (similar to dental novocain), demerol or other morphine-like drugs, midazolam or Versed (similar to Valium), and metaproterenol or similar agent to dilate bronchial airways. If you have an allergy to any one of these or similar types of medications, please inform your surgeon(s) prior to the procedure. If a reaction occurs, you could develop a rash, swelling, nausea and/or vomiting, an unusual feeling, and even wheezing and/or shortness of breath. A reaction is treated by stopping any and all offending medications, and, if necessary, by

giving you other medications to control your symptom(s).

10. **Discomfort** may occur following the procedure. General anesthesia is used to eliminate any discomfort during the procedure; however following the procedure, you may experience slight throat discomfort with or without a dry cough and even hoarseness for one or more days. This is normal and usually is easily controlled by over-the-counter analgesics, such as acetaminophen (Tylenol). Sometimes a stronger medication may be necessary and a prescription for one will be provided for you by your surgeon(s). If you have had a biopsy, you should not use aspirin, anti-inflammatory medications (NSAID's, ie, Advil, Aleve, Vioxx, etc.), or blood thinners (ie, coumadin, heparin, etc.) unless specifically approved by your surgeon(s).

11. **Death.** Life-threatening complications leading to death following mediastinotomy are very rare (<0.1%).

Alternatives

The alternatives to mediastinotomy include the following limited options:

1. Radiologic evaluation of the lymph nodes can be accomplished with computed tomography (CT or "CAT"), magnetic resonance ("MR"), and positron emission tomography (PET) scans. These scans, however, can not detect small abnormalities and also cannot be used to obtain a biopsy of the lymph nodes.
2. Bronchoscopy can be performed and biopsies of certain lymph nodes can

be obtained with the use of small needles inserted through the wall of the airway. Due to the small amount of tissue obtained by this method, the results are frequently inadequate and certainly far less accurate than those obtained with mediastinotomy.

3. Close medical observation can be used to assess airway problems and their developments over time without invasive procedures, however, the main risk of this approach is irreversible progression of disease, ie.,

spread of cancer, lung scarring (pulmonary fibrosis), airway destruction (bronchiectasis), etc., leading to permanent respiratory disability and/or death.

If you decide not to have this procedure, there may be associated risks to this decision. Please discuss it with your doctor.

I discussed the above risks, benefits, and alternatives with the patient. The patient had an opportunity to have all questions answered and was given a copy of this information sheet.

Physician Signature

Date

Patient Signature

Date