

INFORMED CONSENT INFORMATION

ADDRESSOGRAPH DATA

CERVICAL MEDIASTINOSCOPY WITH BIOPSY

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 visualization (mediastinoscopy) and possible sampling (biopsy) of the lymph nodes 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 rigid tube with a light and video camera (mediastinoscope) is inserted through a small 1 inch incision just above your breastbone and passed along the outside of your airway. 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 lymph node(s). In some cases, your surgeon(s) may also pass the mediastinoscope between some of the large blood vessels to get to specific lymph nodes generally not available during a normal examination (extended mediastinoscopy). This is particularly useful in diseases involving the left lung. 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 mediastinoscopy 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. Mediastinoscopy 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. Mediastinoscopy with biopsies may establish a diagnosis, which could substantially change your future treatment and prognosis.
- 3. Mediastinoscopy with biopsy, in unusual cases, may improve airflow into and out of the lungs by removing

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large fluid collections or masses that compress the airway, 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 bleeding chance of increases if biopsies multiple are performed. Although any bleeding that may occur usually amounts to only a few ounces blood: (30-90)cc) of in circumstances, bleeding can become life-threatening, significant and requiring your surgeon(s) to make a large incision through your breastbone (median sternotomy) to stop the Occasionally, bleeding. small а of bleeding after the amount 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, anti-inflammatory certain 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 are taking any of these you please medications. inform vour 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 have and 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), blood-borne infection. 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 mediastinoscopy. Possible infections include an infection in the incision, an infection maior airwavs of the (bronchitis) 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. 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

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- 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 mediastinoscopy. This does not occur very frequently but is more likely if you have a prebreathing existing problem, asthma, emphysema, "COPD", etc. experience You could wheezing and/or chest tightness. During the procedure you will be given additional oxygen to breathe, and in simple medications help your cases, to 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 mechanical ventilator.
- 6. Abnormal heart beats (arrhythmias) during almost can occur procedure done on the chest but are rare during mediastinoscopy. You are more likely to develop arrhythmias if you have had one previously or have significant heart problems. If they do experience occur. may vou palpitations require and could medication to stop or control the

- abnormal heart beats. Most that occur are arrhythmias easily treated, are temporary (lasting only minutes to hours), and are not necessarily an indication of a serious underlying heart problem. In circumstances, arrhythmias can lead to low blood pressure requiring the brief application of an amount of energy electrical 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.
- 7. Leakage of air from the lung or from the mediastinoscope into the sack surrounding the lung with collapse of the lung (pneumothorax) occurs rarely shortly during following or This procedure. usually occurs following a biopsy. 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.
- occur only 8. **Medication** reactions following rarelv during or mediastinoscopy. The medications commonly used are widely available and include lidocaine (similar to dental novocain), demerol or other morphinelike 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 all offending stopping any and medications, and, if necessary, by giving you other medications to control your symptom(s).

9. **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 Sometimes (Tylenol). 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, specifically heparin, etc.) unless approved by your surgeon(s).

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

Alternatives

The alternatives to mediastinoscopy 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, cannot detect small abnormalities and also cannot be used to obtain a biopsy of the lymph nodes.
- 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 mediastinoscopy.
- 3. Close medical observation can be used to assess airway problems and their developments over time without invasive procedures, however, main risk of this approach irreversible progression of disease. ie.. spread of cancer, lung scarring (pulmonary fibrosis), airway destruction (bronchiectasis), etc.. respiratory permanent leading to 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 alterna patient had an opportunity to have all questions and of this information sheet.	• • • • • • • • • • • • • • • • • • •
Physician Signature	Date
Patient Signature	Date

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