

BRONCHOSCOPY WITH OR WITHOUT 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 (bronchoscopy) and possible sampling (biopsy) of your airway. This is performed in the evaluation of cancers, infections, and other respiratory diseases. During the procedure, a flexible (and/or in certain circumstances, a rigid) tube with a light and video camera (bronchoscope) is inserted into your throat either through the mouth or nose and is used to evaluate the inside of your airway from your vocal cords down into each lung. Your surgeon(s) may find it necessary and prudent to obtain a biopsy, which is done with a miniature device specifically made to take a small sample from the inside of the airway. The procedure can last from a few minutes to as long as 1-2 hours, depending on the individual patient's circumstances. The procedure often can be accomplished under local anesthesia (with or without intravenous sedation) but in selected conditions general anesthesia may be necessary.

Benefits

Some benefits that may be gained from undergoing bronchoscopy 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. Bronchoscopy with or without a biopsy may yield important information about established and/or new (unsuspected) diseases involving your airway which

- might not be detected by any other test(s) and/or x-ray(s).
2. Bronchoscopy with biopsy may establish a diagnosis, which could substantially change your future treatment and prognosis.
 3. Bronchoscopy with biopsy, in unusual cases, may improve airflow into and out of the lungs by removing obstructing tissue/material, 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 airway may occur during or following the procedure. The chance of bleeding increases if a biopsy is performed. Although any bleeding that may occur generally amounts to only a few teaspoons of blood, even a small amount of blood in the airway can potentially lead to blockage, breathing difficulty, and (rarely) death. If bleeding does occur, the blood is normally suctioned from your airway until all bleeding stops; however, you will likely cough (expectorate) bloody phlegm for a few days or up to two 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 bronchoscopy regardless of whether a biopsy was performed. Possible infections include an infection of the major airways (bronchitis) and an infection of the lung itself (pneumonia). Infections at insertion sites of intravenous catheters (i.v.'s) also occur. Rarely, sinus infections can occur if the bronchoscope is passed through the nose. 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 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. **Breathing difficulty** with or without a low blood oxygen level may develop

during or following bronchoscopy. 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.

5. **Abnormal heart beats** (arrhythmias) can occur during almost any procedure done on the chest but are rare during bronchoscopy. 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.

6. **Leakage of air from the lung** into its surrounding sack with collapse of the lung (pneumothorax) occurs rarely during or shortly following the procedure. This 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.

7. **Medication reactions** occur only rarely during or following bronchoscopy. 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).

8. **Discomfort** may occur during and following the procedure. Local (topical)

anesthesia with intravenous sedation or, in some cases, general anesthesia is used to minimize any discomfort during the procedure. You are encouraged to communicate any discomfort that you might have during the procedure to your surgeon(s). 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). 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).

9. **Death.** Life-threatening complications leading to death following bronchoscopy are extremely rare (<0.01%).

Alternatives

The alternatives to bronchoscopy include the following limited options:

1. Radiologic evaluation of the airways can be accomplished with computed tomography (CT or "CAT") and MRI ("MR") scans. These scans, however, can not detect small abnormalities and also cannot be used to obtain a biopsy of the central airways. Abnormalities at the edge of the lung can be biopsied with small needles guided by these scans, but the risks are essentially the same and may even exceed those of bronchoscopy.

2. 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