

Radiotherapy Treatment without Tissue Diagnosis

General indications for the proposed procedure/treatment:

Radiotherapy is done in an effort to treat a tumor (cancer, malignancy). Under normal circumstances, a piece of tissue is obtained (a biopsy) or a group of cells from fluid or tissue (cytology) is examined to confirm cancer is present and also to provide valuable information about the type of tumor. This information is important because it can lead to major changes in how the patient is treated. Obtaining tissue can also reveal that the patient does not have a tumor, but rather has some other process ongoing that was suggesting cancer. Because of these experiences and concerns, doctors almost always advise biopsy or cytology proof that a cancer is present before beginning treatment. There are however, a few exceptions to this.

1. Sometimes the clinical presentation, physical findings, and imaging are so characteristic and specific and the risks of obtaining a diagnosis are so great that treatment is routinely done without obtaining tissue. There are only a few situations like this. They usually involve the back of the eye, the main nerve to the eye (optic nerve), or the brainstem. **This form is not intended for patients with one of these situations.**
2. When the situation is so urgent and dangerous that immediate treatment is felt to be necessary to preserve life or function and there isn't time to get a biopsy done and wait for the results. Sometimes in this situation biopsies are obtained and treatment is begun before the results are known.
3. When getting the biopsy is too dangerous because of some other problem such as blood clotting problems, severe infection, or problems with other organs.
4. When a biopsy could be done but the patient refuses the biopsy. If the patient still seeks treatment on the presumption of cancer, then the patient may be making a bad decision for several reasons. For example, the patient may not have cancer, the patient might have a different cancer than what the doctors are guessing, correct treatment might be delayed or not given, the problem might get worse, and/or the patient may experience unnecessary side effects. Some of these side effects could be severe or life threatening.

Description of the proposed procedure/treatment:

The treatment will be based on the cancer situation presumed to be present as suggested by the available clinical information.

Material risks and benefits of the procedure:

The risks of radiotherapy treatment without tissue diagnosis include all of the same risks that would be present if a tissue diagnosis had been obtained confirming the doctors' clinical diagnosis of tumor and type of tumor. However, there is the additional risk that the course of treatment may not be correct because whether there is a tumor, and if there really is a tumor, what type of tumor it is, are not proven. Similarly, the potential benefits of radiotherapy may also be diminished for the same reasons.

Procedure alternatives, if any:

The alternatives to radiotherapy without a tissue diagnosis would be to attempt to obtain a tissue diagnosis. The other alternative would be not to perform radiotherapy. If this form is being provided because of reason 2 or 3 above (urgency of treatment need or unusually high risk of trying to get tissue or cytology), then proceeding without a tissue diagnosis (or before the results of a biopsy have been obtained) may still be the best medical choice. If this form is being provided because of reason 4 (refusal of biopsy based on personal preference), then the patient should be aware that proceeding without tissue diagnosis is not medically the best course of action.

Probable consequences of refusing the recommended procedure:

If a tumor is present and is either not treated in some way or not treated in the best way, the chances that the tumor will continue to grow are increased. This may also increase the chance that the tumor will spread to other parts of the body and eventually cause death. If there is a serious medical condition mimicking a tumor that is not correctly diagnosed and treated, then this condition may worsen and cause additional, potentially serious or life threatening problems.