The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: CASE 5217 - Endoesophageal Brachytherapy for patients with Esophageal cancer: A Balloon repositioning, multi-channel radiation applicator for optimizing treatment delivery

Sponsor: None

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Cancer research studies are coordinated by physicians and scientists form Cleveland, Clinic, University Hospitals, and Case Western Research University through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaborative is the enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic Florida

Participation
You are being invited to participate in a research study. Depending upon your cancer stage, esophageal cancer can be treated with surgery, chemotherapy, radiation therapy, or a combination of these modalities. Sometimes in addition to external radiation therapy or instead of external radiation therapy, select patients with esophageal cancer may benefit from localized radiation to the tumor, called esophageal brachytherapy. There are many different radiation techniques and delivery approaches for this type of specialized radiation therapy, and the purpose of this document is to provide a written summary of a research study investigating a delivery method for brachytherapy developed at our institution. This document is also for use as a reference for the future.

Please note:

- **You are being asked to participate in a research study / Innovative Practice Project. You qualify for this treatment approach based on your current cancer diagnosis**
- **Ask as many questions as needed so you can make an informed decision**
- **Carefully consider the risks, benefits, and alternatives of any treatment**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw consent for brachytherapy at any time.**

1. INFORMATION ON THE ROLE OF ESOPHAGEAL BRACHYTHERAPY TREATMENTS

Why is this research being done?

Many patients with esophageal cancer will benefit from esophageal brachytherapy treatments (localized radiation) as it allows your physician to deliver high doses of radiation directly to the tumor, but minimize the doses of radiation to the nearby normal organs (such as the trachea, heart and lungs). There are many different methods of delivering this localized radiation therapy and they are institution and practitioner-dependent.

Despite the benefits that these localized radiation treatments may add to cancer care, there are many drawbacks to the original delivery approach due to treatment-related side effects. At our institution, we currently utilize three commercially available single treatment applicators (tubes) taped together through which radiation therapy is delivered using a radioactive seed. Other institutions use a single commercially available treatment applicator to deliver the radioactive seed. Our initial results with the three applicator approach have demonstrated favorable treatment outcomes and low rates of side effects and have been presented at national conferences.

In an effort to further improve on our treatment technique, we have created a balloon repositioning, multichannel brachytherapy applicator which has 6 channels instead of 3-tubes. This prototype was tested in a pig model and showed ease of placement of the device and has been further tested by our medical physics team. This study will be the first use of the 6 channel balloon repositioning, multichannel brachytherapy applicator in humans. The applicator is not FDA approved.

The purpose of this research is to collect and analyze data on radiation dose distribution using the applicator. Additionally, patient outcomes to assess the safety and efficacy of this new treatment approach compared to other approaches.

What is involved if you decide to be treated with this new device?

The entire process and treatment procedure will be similar to our standard brachytherapy treatment procedure. The only difference is the use of this new prototype brachytherapy applicator instead of the 3-tube technique. It is summarized below in two main sections.

Intraoperative procedure:

- In the operating room, your pulse (heart rate), pulse oximetry (oxygenation), and blood pressure are measured.
- You are given anesthesia medications per the standard operating procedure per your provider and institution.
- You undergo an upper endoscopy, in which a thin scope with a light and camera is used to look inside the esophagus and stomach.
- Once the area of the cancer is identified, metallic clips are placed above and below the tumor which can be seen on x-rays and CT scans to aid in radiation planning.
- The radiation therapy brachytherapy applicator is then placed into the esophagus and stabilized by inflating the anchor balloon.

Radiation therapy procedure

- You will undergo a CT scan in the Department of Radiation Oncology to plan the radiation therapy.
- Your radiation oncologist will design a specialized radiation treatment plan to treat your tumor based on your specific anatomy.
- You will be transported to the treatment room at which time you will undergo the radiation treatment which typically takes 10-15 minutes.
- After treatment, the brachytherapy applicator will be removed from you.
- You will stay in the department for approximately one-half hour afterwards for monitoring.

2. ALTERNATIVES

What are the alternatives to this treatment?

Radiation therapy treatments for your cancer include external radiation and internal radiation treatments. Your cancer physician will decide which approach is the best for you.

For patients undergoing this localized radiation treatment, the alternative would be treatment with our institutional 3-tube approach.

3. RISKS

What are the risks of opting for treatment with this new device?

- The endoscopy portion of the procedure remains unchanged and will be performed in accordance with the standard of care with the exception of placement of the 6 channel applicator for brachytherapy.
- The 6-channel applicator consists of two balloons constructed of commercially available, medical grade materials.
- The risks associated with this applicator should be similar to risks of the currently used 3-tube model in our department.
- The applicator is not intended as an implant; it will not remain in you after the procedure is completed. The applicator can be easily and quickly removed at any time during the procedure.
- One of the risks associated with radiation exposure is cancer. Use of this device is not associated with any increased risk of radiation exposure compared to the currently used 3 tube applicator.
- There may be unforeseen risks to an unborn child if you become pregnant during radiation therapy. Therefore, if you are capable of giving birth to or fathering a child, you and your sexual partner should use adequate birth control measures while you receive radiation therapy. These measures may include abstinence, oral contraceptives (birth control pills), IUD, diaphragm, approved hormone injections, condoms, or medical sterilization. If you are unwilling to do this, we ask that you not undergo radiation therapy. If you or your spouse becomes pregnant while undergoing radiation therapy, you must notify the study doctor immediately.

4. BENEFITS

What are possible benefits of use of the 6 channel balloon repositioning, multichannel brachytherapy applicator?

You may not receive any direct benefit from use of the applicator. The study is investigating radiation dose distribution and may find there is improved radiation distribution to the tumor and a decrease in the side effects of the brachytherapy.

5. COSTS

Are there any costs to you?

The treatments you will receive are considered to be routine clinical services that you would have received otherwise. Therefore, they will be billed to you or your health insurance plan. You are responsible for any deductibles or co-pays as a result of radiation therapy. There are no additional costs/ charges for use of this device.

6. COMPENSATION

Are there any payments to you?

There is no direct compensation provided to you by using this device.

7. TREATMENT RELATED INJURY

What will happen if you are injured as a result of this treatment?

In the event you are injured as a result of this procedure, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for an injury related to this device use. You are not waiving any legal rights by signing this form.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected?

<u>HIPAA Authorization (Privacy and Confidentiality)</u>

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to John Greskovich MD, and the research study staff at Cleveland Clinic and/or University Hospitals for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.
In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board, and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- Case Comprehensive Cancer Center members and collaborators
- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Other Institutional Review Boards;
- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

John F. Greskovich, MD
Cleveland Clinic Florida
2950 Cleveland Clinic Blvd.
Weston, FL 33331

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic and/or University Hospitals cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

9. CONFLICT OF INTEREST

Do the providers have any conflicts of interest relating to this treatment approach?

None of your treating physicians have any financial conflicts of interest related to this specific treatment approach.

10. QUESTIONS

Who do you call if you have any questions or problems?

Please contact your physician's office at 954-659-5840 if you have any questions. The radiation oncologist physician on-call can be reached at 954-659-5000 if you have any urgent or immediate questions or concerns. If you have questions about your rights as a research subject, please contact the Institutional Review Board at 1-800-223-2273 x42924.

11. VOLUNTARY PARTICIPATION

What are your rights?

Electing to be treated with the new applicator is voluntary. You will be told of any new or relevant information as experience grows regarding this technique that may affect your health or welfare.

Any time prior to the procedure, you may contact your provider if you change your mind regarding this treatment approach.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

12. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to be treated with the new brachytherapy applicator device.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this procedure.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

Legally Authorized Representative (LAR)

You have had the above procedure explained to you and as an individual likely to understand the subject's situation and acting in their best interest, you give your permission (or authorize) for this treatment.

_____
Printed Name of Subject

_____ _____
LAR Signature *Date*