



Pacific Northwest Laboratories

REPOSITORY PNL

COLLECTION Intraesophageal

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FOLDER HSC 73-5

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Project Number PNL-9208

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Date April 16, 1973

To Dr. W.J. Bair

From K.L. Swinth *K.L.S.*

Subject Human Research Committee Approval for Intraesophageal Radiation Detector

I would like to request the approval of the human research committee for the evaluation of developmental intraesophageal radiation detectors in human volunteers. The attached reprint describes the problem in the introduction and gives some results with earlier probes. We do not intend to use the avalanche detectors described in the report under this approval. The probe we will use is a 7 mm diameter by 3 cm long NaI(Tl) scintillator cemented to a flexible fiber optics light pipe with a diameter of about 6 mm. The probe is a non-conductor and is completely passive in nature. All voltages and electronics will be external to and remote from the subject being counted. In contrast, the earlier avalanche probes involved a voltage of 1-2 kilovolts on the internal detector. Even with this potentially more hazardous detector we did not experience any problems in animal experiments.

The fiber-optics probe is about 30 times as sensitive as the avalanche probes, but does have a slightly higher background. With tests in a phantom made to simulate the area of interest, I predict an MDA of 1.3 nCi to 2.9 nCi (depending on counting conditions) compared to ~ 26.4 nCi for the avalanche probes.

We have performed a number of experiments on dogs at the Battelle Biology Department with both types of detectors. The procedure does not seem to be traumatic to the animals and the experiments have proven the validity of the concept. In the dogs the probe was inserted into the esophagus and counts taken as the probe was moved up and down the esophagus. This allowed us to locate the area of maximum count rate which was shown to be the area of the tracheal bifurcation by x-rays. This is the location of the major mass of the lymph nodes draining the lungs.

In the human experiments our tentative protocol is as follows.

- 1) Examining physician will obtain informed consent and determine any contraindications for either the probe insertion or administration of an anesthetic. Some typical contraindications would be; aneurysm, dysphagia, esophageal diverticulum, hiatus hernia, recent history of swallowing corrosive poison, angina pectoris, severe dyspnea, severe kyphoscoliosis, cardiospasm or reaction to anesthesia (see below). Any subject who shows extreme reluctance to swallow the probe will not be coerced into doing so.
- 2) Administer a local anesthetic to aid in passing the probe. Either a flavoured viscous jell containing xylocaine, and made for this purpose, or a topical anesthetic spray will be used. Recent conversations indicate an anesthetic is probably unnecessary; however, a small amount may prove a significant psychological aid to the subject.

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- 3) Following the patient preparation, the probe will be inserted about 30 cm as referenced to the front teeth. The probe will be lightly coated with a hospital lubricant to ease passage.
- 4) Next the subject will be fluoroscoped long enough to assure that the detector is positioned at the bifurcation. The detector will be in the correct position when its distal end is about 1 cm below the common segment of the major bronchii. On reexaminations it will be possible to forego the fluoroscopy and if the depth of the bifurcation proves relatively constant it will be possible to forego fluoroscopy altogether after the initial cases.
- 5) Next the subject will be placed in a comfortable position and two 10 minute recordings of the count rate will be made. The probe will then be inserted an additional 4 cm for a 10 minute count and finally will be withdrawn 8 cm for a 10 minute count. This will complete the experiment and the probe will be withdrawn and the subject examined by the attending physician.

#### Discussion of Procedure

We have discussed the procedure with Dr. Whitaker (Head of ENT at the Los Angeles County Medical Center) and Drs. Haubrich and Crosby at Scripps Clinic and Medical Research Center. They all consider the procedure simple with minimal risk to the patient. In fact, it has been suggested that I become familiar enough with the procedure to perform the probe insertion. Dr. Crosby who we were referred to by Dr. Goldstein (AEC) demonstrated the ease of the technique by swallowing the probe unaided, a task I have not been able to accomplish to date. Dr. Crosby is a hematologist who developed the Crosby capsule for gastrointestinal biopsy and he has had considerable experience in such matters.

From the discussions, I believe the procedure is primarily an education of the subject and helping him to learn to accommodate the probe. We hope to observe gastroscopies on patients before we attempt measurements on any subjects. This will also be an ideal time to obtain background count rates.

Gastroscopy is an old procedure dating back to the 1920's. Initially a rigid metal tube was used and this involved some definite risks. Three types of severe lesions were observed: 1) lesion of the hypopharynx, 2) rupture and perforation of the thoracic esophagus and rupture and perforation of the stomach. In our case we do not have to worry about lesions 2 and 3 since we will not enter the stomach and ruptures of the esophagus usually occurred in the last 2-3 cm where it curves before entering the stomach. The most common site of perforation with the solid gastroscope was the pharyngoesophageal region with an overall accident rate of 0.079% and a fatality rate of 0.014% (C.H. Brown ed., Diagnostic Procedures in Gastroenterology). It must be emphasized that these accident rates are before the introduction of the flexible gastroscope and the foregoing is primarily historical information. Any accidents are rare with the flexible gastroscope (R.S. Nelson, Gastroscopic Photography) which is similar to the probe we are working with. In fact one expert states, "In 1,300 examinations with the rigid gastroscope and in 6,000 with the flexible gastroscope, I have not seen this lesion (lesion of hypopharynx) even once..." (R. Schindler, Gastroscopy). The likely lesion of the hypopharynx is crushing the tissue between a rigid probe and the spinal column.

To summarize the preceeding discussion, we should not experience any difficulty with our flexible probe. The greater danger is a reaction to any anesthesia employed. Another factor in our favor is that we will be working with healthy individuals.

Presently it is not clear where subjects will be obtained. The prime sites are BNW, LASL and Dow Chemical (Rocky Flats Div.). We intend to allow the AEC to aid in identification of appropriate subjects.