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MED 6000-3 Part I
CLINICAL INVESTIGATION STUDY PROPOSAL

CID # 003
Date: 25 Mar 86

- I. Activity: Clinical Investigation Department, Naval Hospital, San Diego, California 92134
- II. Title: Utility of Endoscopy for X-ray Negative Dysphagia: A Prospective Analysis
- III. Investigators:

Principal: J. Mark Lawson, LCDR, MC, USN
Fellow, Division of Gastroenterology
Department of Internal Medicine

Percent of time required: 5%
Projected rotation date: July 1987

Associates: Michael M. Mottet, CDR, MC, USN
Head, Division of Gastroenterology
Department of Internal Medicine

Percent of time required: 1%
Projected rotation date: June 1988

Richard Brower, LCDR, MC, USNR
Assistant Head, Division of Gastroenterology
Department of Internal Medicine

Percent of time required: 1%
Projected rotation date: Aug 1986

Estimated duration of study: Two years

ENCLOSURE (125)

Identification of Drugs and Devices to be Used in the Study:

- A. Standard UGI panendoscope. Light sedation with Valium or Valium and Demerol in combination. Sedation with these medicines are a routine part of panendoscopy. Atropine 0.6 mg will also routinely be used to control secretions and motility.
- B. Esophageal manometry using a low compliance hydraulic perfused catheter system (Arndorfer Medical Supply).

V. Methods and Materials:

- A. Objective: To evaluate the need for endoscopy and manometry in patients with X-ray negative dysphagia. Specifically, the following questions will be addressed: How frequent are significant lesions found by UGI endoscopy, how frequently is treatment changed in the patients studied with UGI endoscopy, how frequently will manometry provide additional information, and what is the cost of finding a significant lesion with X-ray negative dysphagia.

B. Background:

1. The symptom of dysphagia is a strong indicator of esophageal disease. Because of the reliability of this symptom for the presence of disease, it is currently recommended that all patients undergo endoscopic evaluation, even when a normal barium study has been obtained.^{1-5,9,10} The recommendation stems from reports of endoscopically diagnosed esophageal cancers in patients with negative barium esophageal studies.⁶ Recently this dogma was questioned in a retrospective review of 195 cases of patients with X-ray negative dysphagia who went on to have upper endoscopy.¹⁰ In no patient was esophageal carcinoma found, and when patients with hiatal hernias or low grade esophagitis were eliminated, only eight patients had an endoscopic abnormality missed by the esophagram. These lesions included three peptic strictures, and single cases of candidiasis, an inflammatory polyp, a mucosal B ring, varicies, and esophageal cyst. The authors concluded that a reassessment of the necessity for endoscopy in these patients was in order, particularly in this era of diagnostic restraint.

2. At the Naval Hospital, San Diego, the Gastroenterology Division sees a great number of patients with a principal complaint of dysphagia. Many of these patients have already had barium X-ray studies of the esophagus. Our current policy, in accordance with the recommendations of the American Society for Gastrointestinal Endoscopy, is that these patients undergo upper endoscopy. If normal, esophageal motility studies are also frequently done to search for motor disturbance as the etiology for the patient's symptoms.

3. Upper endoscopy is a well accepted diagnostic tool with an overall complications rate of .13%. The most common of these complications is a medication reaction. Currently, upper endoscopy is the gold standard by which other diagnostic procedures for anatomic esophageal diseases are measured. The cost for this procedure in the civilian community is not inconsequential and not available at many smaller Naval Hospitals. Clarification of the need for endoscopy in X-ray negative patients could help reduce health care cost, prevent unnecessary procedures, and assist Navy physicians at smaller hospitals in evaluating patients with dysphagia. Complications secondary to esophageal manometry are minor and usually consist of pharyngeal irritation and occasionally vomiting.
4. Approach: Patient population
Inclusions:
 - (a) All adults, greater than 18 years of age, male and non-pregnant females with the symptoms of dysphagia and a negative barium swallow. Also to be excluded will be uncooperative patients or patients with unstable cardiopulmonary disease. Radiographic gastroesophageal reflux or a hiatal hernia will be considered normal findings for the purpose of this study.
 - (b) Informed written consent to participate in the study. The number of patients to be enrolled is 113. (See statistical analysis.)
5. Study Methods: All patients will be evaluated by members of the Gastroenterology Division. The medical care of these patients will not be altered by inclusion in this study protocol. A history of dysphagia and a negative barium swallow (excluding radiographic reflux or hiatal hernias as positive findings) are requirements for enrollment. All barium swallow studies will be reviewed by one radiologist to reduce the variability of readings. Should other hospitals participate in this study one radiologist from each institution will be selected to review those studies. Patients with positive X-ray studies will also be endoscopically studied but not included in this protocol. These patients then will undergo upper endoscopy. If following a barium swallow and an upper endoscopy no pathologic lesions have been identified, esophageal motility to assess the lower and upper esophageal sphincter pressures and relaxation, the amplitude, duration, and timing of the esophageal waves will be performed. The results of these tests will be documented in the patient's health record. The physician will fill out the data collection form which includes a pre- and post-procedure diagnosis and therapy entry.