SWALLOWINGNEWS

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Director's Forum

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STENTS FOR ESOPHAGEAL CANCER: THEIR EXPANDING ROLE

Three major problems confront the patient with advanced esophageal cancer: difficulty swallowing (dysphagia), chest pain and malnutrition. Each of these requires a different primary therapy, although relief provided for one may benefit the other two. All three of these sequelae of malignant growth may be present at some time in most patients.

Dysphagia tends to receive the most emphasis because it is so dramatically manifest and easily correlated with demonstrable disease. Chest pain receives less emphasis because it is subjective, and more difficult to correlate with the disease. Malnutrition often receives insufficient attention because the patient's condition is attributed to "cancer", with a failing to recognize that such debility usually is due in large part to protein-calorie malnutrition resulting from both dysphagia and anorexia (lack of appetite). It should be recognized that suffering in these patients may be as often due to the consequences of malnutrition and the sequelae of its related immunologic incompetence as from the growth and spread of the primary malignancy.

A major complication of esophageal carcinoma is the development of an esophagopulmonary fistula (opening or hole between esophagus and trachea) that often leads to pneumonia. A fistula develops in about 15% of cases and usually should not be attributed to anything other than the natural history of this disease. Fistulas are the consequence of tissue destruction by carcinoma invading normal tissue. They may first become manifest after radiation therapy has produced the desired destruction of the invading cancer. The fistula, however, is not a complication of radiation, dilation or other therapy for this malignancy, it simply is a natural event to be expected when cancer tissue involving the esophagus and adjacent trachea necroses (dies) spontaneously or after chemotherapy or radiation therapy and is removed or displaced. When the necrotic tissue is displaced an esophageal-pulmonary fistula then becomes clinically obvious when the patient coughs immediately after swallowing either saliva, liquids, and to a lesser extent solid food. The development of a fistula rarely is the result of faulty diagnostic or therapeutic technique.

Most patients with esophageal cancer will need palliation for obstruction or leakage through a fistula. Some modern radiation and chemotherapy regimens offer a reasonable chance for palliation. The side effects of radiation and chemotherapy can be managed well by alterations of dosage and frequency and certain drugs. In selected patients with operable lesions, surgical therapy may offer good palliation of dysphagia at the price of operative risk and post-resection sequelae. Peroral dilation should be used to restore patency prior to nonsurgical therapy and later as needed to maintain patency before or after other methods of treatment.

Other methods available for relieving symptoms of malignant esophageal obstruction include brachytherapy (radiation from inside the esophagus), prostheses or stents, laser (thermal Nd:YAG and photodynamic therapy or PDT), and chemical injections. The technique selected varies with the expertise available at each institution. Each method has its benefits and risks.

Stenting devices or prostheses and their introduction techniques for palliation of esophageal cancer have been improved and used with increasing frequency during the past thirty years. The singular purpose of an esophageal stent placed via the mouth is to safely open and maintain the obstructed esophagus to a lumen diameter sufficient to allow the pleasures and potential nutritional benefit of oral food intake, and to reduce the risks of aspiration into the lungs. Without an adequate esophageal lumen, patients suffer great misery from dysphagia, sialorrhea (excessive salivation), regurgitation of saliva and food, malnutrition, cough and pneumonia. The type of therapy selected to keep the esophagus open is based on the potential that it offers for dysphagia relief with the least complications, hospital confinement and cost. The bottom line on stents is that they meet these criteria and will improve the quality if not the quantity of life.

Esophageal stents provide palliation and survival time similar to laser and other techniques designed to reduce dysphagia. Those who treat malignant esophageal obstruction are well aware that dysphagia relief does not equate with relief of anorexia, nutritional restoration or prolonged survival, but does allow the patient to enjoy the pleasures of oral alimentation and less time in the physician's office or hospital. At present, too few patients are informed of, or given the option to have, a peroral esophageal stent placed early enough to provide optimum benefit. Both plastic and metal-expandable stents can be used to provide significant symptomatic relief.

Comments and Concerns with Metal Stents

The availability of well-tested esophageal metal expandable stents offers great promise, but only if both the stent devices and the "stentor" physician are properly prepared to offer such important palliation for malignant esophageal obstruction in a safe, thoughtful and cost-effective manner.

Esophageal stents are placed via the mouth after the obstructing tumor has been dilated to a proper size. Such dilation often requires several sessions. The placement is conducted under fluoroscopic control with the patient properly sedated. Placement time is less than 1 minute for plastic stents and less than 5 minutes for metal expandable stents. Complications associated with stent placement, such as perforation, should be less than 5 percent. Patients are observed in the hospital for one to two days after placement and are given special dietary instructions.

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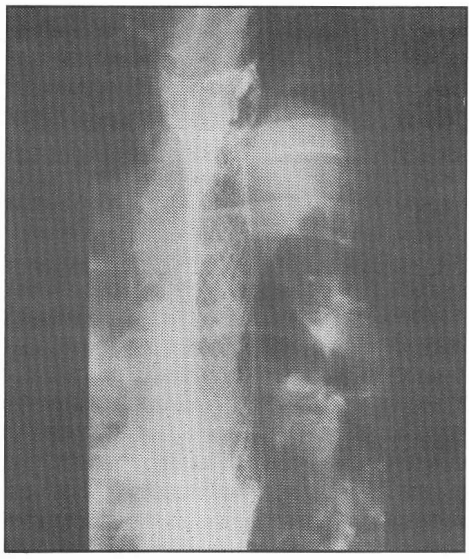

Chest x-ray showing expandable metal stent in place. The patient does not sense the stent in proper position.

The most reasonable palliation of the problems of malignant esophagopulmonary fistulas (opening between esophagus and trachea) is an esophageal stent - plastic, balloon or coated metal expandable. Effective occlusion of a fistula within minutes by proper stent placement is one of the most dramatic and satisfying therapeutic ventures in medicine. The elimination of cough, the reduction of sialorrhea and tracheobronchial aspiration, the restoration of ability to rest and sleep without the constant cough, the improvement in quality of life and psychological status of patient and family provide a wonderfully comforting experience for all concerned.

The marvelous potential benefits of the ideal stent for the patient with esophageal cancer will be easy, rapid and safe placement, restoration of a predictable and adequate lumen size, optimal palliation of dysphagia and sialorrhea, or occlusion of tracheoesophageal fistulas, and provision of the best possible quality of life.

PROTON PUMP INHIBITORS

Umesh Choudhry, M.D.

For over 15 years histamine (H_2) antagonists such as Zantac, Tagamet, Pepcid, etc. have been the first line of treatment of peptic ulcers and gastroesophageal reflux disease. Recently, a more powerful group of acid suppressants has become available for treatment of these disorders. This group is collectively referred to as proton pump inhibitors (PPI). Two agents of this group available commercially are: omeprazole (Prilosec) and lansoprazole (Prevacid). Chemically these agents belong to a new class of drugs called substituted benzimidazoles and are closely related.

Mechanism of Action:

These drugs act by specific inactivation of an enzyme system (H+/K+ ATPase) at the surface of the acid producing cells of the stomach. This enzyme system has been characterized as the acid (proton) pump of the stomach. Hence the name, proton pump inhibitors.

Pharmacokinetics:

Both drugs are available as capsules which contain an enteric coated granule formulation of the drug. These granules protect the drug from being deactivated by acid in the stomach. Absorption begins once the granules reach the small intestine. Both drugs are rapidly absorbed and attain their peak concentrations within 0.5 to 3.5 hours. Both drugs are best absorbed when given in a fasting condition, 30 minutes before a meal (usually breakfast). They are excreted primarily by the liver. Their duration of acid suppression lasts nearly 24 hours with peak acid suppression occurring within six hours.

Both drugs cause a significant increase in concentration of gastrin, a hormone produced by the stomach. Both drugs in very high doses given to rats caused formation of carcinoid tumors in the stomach. These tumors have not been reported in humans despite continued use of omeprazole in millions of patients over the past 7 years. Lansoprazole, a relatively new agent, has been used in thousands of patients worldwide with no evidence of these tumors.

A recent, small European study reported development of atrophic gastritis in patients infected with a bacterium (Helicobacter pylori) and on long-term treatment with Prilosec. This has not been reported by any well designed large clinical trial from the United States. The present evidence for this association is unconvincing. Treatment for this bacterium in the absence of any pathological lesion (ulcer or gastritis) is currently not recommended.

CLINICAL USES:

Prilosec and Prevacid are widely used in patients with stomach and duodenal ulcers as part of regimens directed towards eradicating an ulcer causing bacterium. They are also used in the treatment of ulcers caused by aspirin and its related compounds. The most important and effective use of these medications is for acid reflux or gastroesophageal reflux disease (GERD) and its complications viz. erosive esophagitis, esophageal stricture and Barrett esophagus. These agents are far superior in initiating and maintaining healing of erosive esophagitis, a severe inflammation of the food pipe caused by acid reflux, than other available medications. Some patients with mild GERD respond well to H_2 antagonists. In the treatment of GERD and its complications it is impor-

tant that these drugs be continued on a long-term basis and any changes in the regimen made only on the advice of the physician.

Dosage and administration:

Prevacid, 15 mg, 30 mg and Prilosec, 20 mg. - The capsules are taken by mouth 1/2 hour prior to breakfast to optimize absorption in a fasting state. Patients with difficulty in swallowing these capsules may open the capsules and mix the granules with applesauce or similar food stuffs and swallow the granules. Care should be taken to avoid chewing the granules since the coating on the granules protects the medication from being inactivated by the stomach.

Side Effects:

Both omeprazole and lansoprazole are safe medications. The reported but uncommon (1 to 6.9%) adverse effects are as follows.
Omeprazole: Headache, diarrhea, abdominal pain, nausea, vomiting, rash, constipation and dizziness.
Lansoprazole: Abdominal pain, diarrhea, nausea and headache.Although no adverse events on the human fetus have been demonstrated, these drugs should be avoided in pregnant and nursing mothers.

Drug Interactions:

Although this may not be clinically significant, blood levels of other drugs metabolized by the liver may be altered by concomitant use of Prilosec or Prevacid. Absorption of both drugs may be altered by concomitant use of sucralfate (Carafate). Both drugs in turn may interfere with the absorption of drugs such as ketoconazole (Nizoral), ampicillin, iron salts (Feosol) and digoxin (Lanoxin).

Specific information about individual patients or situations may be obtained from your physician or local pharmacist.

HEALTH INSURANCE
THE MANAGED CARE BATTLE

As all of us are aware, there have been major changes in the health insurance industry with the addition of health maintenance organizations (HMOs), commonly referred to as managed care plans. Those patients who are covered by traditional indemnity or commercial insurance companies have relatively unlimited access to health care providers. Unfortunately, patients who are covered by managed care plans (HMOs, some PPOs) are not so lucky. Managed care plans are designed to control health care costs by controlling where patients receive their care and any referrals to specialized care facilities, such as the Center for Swallowing Disorders, require authorization from the patient's primary care physician. The referral/authorization process can be quite time consuming and there are no guarantees. Having recently encountered a variety of problems with some managed care plans, we hope the following tips will be of benefit to you:

1) ***AUTHORIZATIONS ARE YOUR RESPONSIBILITY.*** It is the patient's responsibility to get authorization or pre-certifications for treatment from the insurance company **before** any treatment occurs. It is not the Center's responsibility to obtain these authorizations. To save time and trouble, call your insurance company and/or primary care physician's office to get these authorizations prior to your scheduled visit. Make sure you receive an authorization number and make sure you call us with the number. **DO NOT WAIT UNTIL THE DAY BEFORE OR MORNING OF YOUR VISIT.** Patients run the risk of being billed directly for services provided if they are not properly authorized. Some companies will penalize the patient a percentage of the cost of care if they do not obtain their authorizations or pre-certifications ahead of time.

If authorizations are not received in a timely fashion, it may be necessary for us to cancel your appointment and reschedule you for a later date. If you need to reschedule your appointment for any reason remember to contact your insurance company/or primary care physician's office to let them know. They may not authorize the rescheduled visit if they are not notified.

2) ***READ AND UNDERSTAND HOW YOUR INSURANCE POLICY WORKS.*** Your insurance policy is a contract. Read it, understand it and ask questions before problems arise. Policies are different and you need to know how it affects your medical coverage.

3) ***DO NOT ASSUME YOUR POLICY COVERS SOME THING.*** Never assume your policy covers everything; make sure you ask questions so you will know exactly what your coverage provides.

4) ***CARRY YOUR INSURANCE CARD WITH YOU.*** Make sure you have your insurance card with you at all times.

5) ***WHEN PROBLEMS ARISE.*** Do not be afraid to ask questions. If you do not think you are being treated fairly by your company or if you are not able to resolve a problem, ask questions. Consider calling the State Department of Insurance Consumer Services Division for information or assistance. Their Tampa number is 987-6741.

6) ***WE ARE HERE.*** We are here to help your company understand what type of visit or procedure you may need. If there is a question concerning the service we will be providing, the company can call us directly at (813) 974-3374.

Things To Remember

1. **OFFICE HOURS:** 8:00 a.m. 'til 4:30 p.m. Monday through Friday.

   Our office is **closed on weekends** so it is important to make sure any medication refills are called to us during our regular office hours.

   Also, our emergency telephone number for after hours is (813) 974-2201. Please remember these calls will be responded to by one of our gastroenterology residents who will in turn contact the appropriate attending physician on call.

2. **BILLING:** Individuals who may have problems with their accounts should contact the Patient Relations Department of the University of South Florida Medical Clinics at (813) 974-3573 between the hours of 10:00 a.m. 'til 4:00 p.m. Monday through Friday. For those patients who are from out-of-town, a new toll-free number has been added for you to call with billing questions. The number is 1-800-933-8672. This number is for calls originating in Florida and is **only for billing questions.**

3. **DILATIONS:** For our patients who receive periodic esophageal dilations: Please try to anticipate and contact our office at least 2 to 3 weeks in advance of your need for dilation, if at all possible. We have been having to schedule routine cases 3 to 4 weeks in advance due to our heavy patient load. We do not want any of you to suffer unnecessarily, so please help us with your appointment needs.

AMBULATORY 24 HOUR pH STUDY *Nancy Kirk, L.P.N.*

The ambulatory esophageal pH study is a test which records the amount of acidity or alkalinity in the esophagus over a prolonged period of time in patients with suspected gastroesophageal reflux. It is the most definitive and sensitive study to detect frequency and duration of reflux events. On the end of the probe or tube used to perform this study is a chemical sensor or electrode which measures pH. Those with swimming pools will recognize the pH (concentrations of hydrogen ions) measurement. It is based on a scale of 0-14. The normal pH of the esophagus is between 5.0 and 7.0. Values below 4.0 are considered to be associated with potentially injurious amounts of acid reflux from the stomach into the lower esophagus. The test involves passing a small tube through the nose and into the esophagus. Sedation is not necessary for this procedure. The tube is connected to a small recorder called a Digitrapper which is worn around the waist (similar to a Walkman radio). The patient completes a symptom diary for the recording period (usually 24 hours) and is encouraged to resume normal daily routine of meals, activity, rest, sleep, etc. The patient records all events and symptoms that may be related to reflux such as heartburn, cough, belch, regurgitation, meals and snacks and periods of rest or sleep in the recumbant position. At the end of the study, a time correlation is made between reflux episodes and symptoms and events listed in the patient's diary.

Patient Preparation for the pH Study

1. Stop medications that might interfere with test results. Please advise the nurse at the time your study is being scheduled of all medications you are currently taking. It is especially important not to take any medications that will interfere with the pH reading, i.e., Tagamet, Zantac, Pepcid, Axid, Prevacid, Prilosec or antacids unless your physician tells you otherwise.
2. It is best to have your stomach empty for at least 3 hours prior to the passage of the tube. Once the tube is in your esophagus you will be able to resume your regular diet.
3. Wear comfortable clothes with a button down front.
4. The patient needs to explain the most bothersome symptoms (i.e., heartburn, cough, chest pain, hoarseness, regurgitation, etc.) to the nurse prior to the study. These symptoms will be recorded by the patient in the diary as they occur throughout the 24 hour period.
5. Do **not** take a shower once the pH probe has been placed.
6. This is an outpatient procedure. You will be advised to return the following day for removal of the tube and review of your diary.
7. There are no restrictions after the study is discontinued and a report will be sent directly to the doctor who referred you for the study. A copy of the report can be sent to any other doctor you wish but you must inform the nurse conducting the study.
8. Resume your prescribed medications after the study is completed.
9. The **Digitrapper** you will wear around your waist is a very expensive and delicate piece of medical equipment. **Please protect it from damage.**

SWALLOWING CENTER CONSULTATION SERVICES

The Director, Dr. Boyce, is a gastroenterologist who specializes in Esophagology (diseases and disorders of the esophagus) and related swallowing disorders. His responsibilities as a physician and professor of medicine are divided among patient care, research and teaching at the USF College of Medicine, and administration of the Center for Swallowing Disorders. These obligations to teaching, research and continuing medical education require travel to participate in national and international meetings. As a consequence, office hours for patient care are not available everyday. Since the Swallowing Center is oriented to manage only complex or unusual swallowing disorders, we are not able to provide primary gastroenterology care. A significant portion of time is spent in telephone discussions and consultations with physicians in Florida and many other states. Since Dr. Boyce is not able to provide primary care, all new patients should have a local primary gastroenterologist who can follow up with Dr. Boyce's recommendations at the completion of the consultation and related care. All records of diagnostic testing, treatment and recommendations will be forwarded to the referring physician(s). Dr. Boyce is available for telephone consultation and will follow patients with more complex needs on a longer term basis as appropriate at the request of the referring physician. Patient referrals are made through the Patient Care Coordinator. All records and x-rays pertaining to the problem are reviewed, if possible prior to the visit, and the patient is interviewed over the phone to help triage appointments based on medical need. Prior review of pertinent medical records and x-rays is necessary to properly schedule and coordinate necessary procedures. The local referring physician will oversee care for the patient until the time of the appointment.

Dr. Boyce's clinics are conducted on Tuesday, Wednesday and Friday. The office of the Center for Swallowing Disorders is open Monday through Friday. Telephone lines are open from 8:30-4:30 Monday, Tuesday, Wednesday and Friday, and from 8:30-12 noon on Thursday. Our number is (813) 974-3374.

Effective July 1, 1996 the Center for Swallowing Disorders will have a second physician specialist in swallowing disorders and esophagology available to provide consultations as well as diagnostic and therapeutic procedures.

Center for Swallowing Disorders
University of South Florida

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