Obstructing Endobronchial Cancer: Dyspnea, photosensitivity reaction, hemoptysis, pyrexia, cough, pneumonia.
Superficial Endobronchial Tumors: Exudate, photosensitivity reaction, bronchial obstruction, edema, bronchostenosis.
High-Grade Dysplasia in Barrett's Esophagus: Photosensitivity reaction, esophageal stenosis, vomiting, chest pain, nausea, pyrexia, constipation, dysphagia, abdominal pain, pleural effusion, dehydration.

Other photosensitizing agents may increase the risk of photosensitivity reaction. Because of the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with PHOTOFRIN and for 5 months after the last dose.

Please see accompanying full Prescribing Information for PHOTOFRIN® (porfimer sodium) for Injection at: www.photofrin.com

FOR MORE INFORMATION about PHOTOFRIN®, or if there are any questions regarding the information provided, visit **www.photofrin.com** or please contact the Medical Information Department at **1-866-248-2039**.
You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

ADP-046 08/2020

Esophageal Adenocarcinoma

Courtesy of Shiro Urayama, MD
UC Davis Comprehensive Cancer Center
Division of Gastroenterology and Hepatology,
Sacramento, CA

Patient History

This 70-year-old male had a long-term history of gastroesophageal (GE) reflux symptoms. While having a Barrett's esophagus surveillance examination, he was found to have distal esophageal adenocarcinoma andwas referred to our institution for subsequent work-up.

Examination

The patient was morbidly obese, diabetic, and had history of significant cardiac history. Therefore, he was not considered to be a surgical candidate.

Diagnostic Evaluation

During initial endoscopic examination, a large, friable, polypoid mass (>2 cm) was noted in the distal esophagus, down to the GE junction within the region of Barrett's esophagus (Figure 1). Endoscopic ultrasound revealed the polypoid lesion to be superficially located without evidence of adjacent lymphadenopathies.

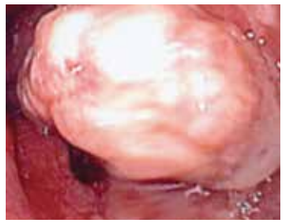

Figure 1 – Polypoid mass noted on endoscopic examination.

Course of Treatment

Based on the above findings, an endoscopic mucosal resection was performed. The histopathology demonstrated presence of cancerous cells in the deep margin of the resection, and it was recommended that the patient undergo additional chemoradiation treatment.

A surveillance endoscopic examination 3 months after the completion of the chemoradiation treatment demonstrated columnar-lined nodular patches suggestive of residual Barrett's-like mucosa (within~5-cm region) in the distal esophagus at the previous site of the mass (Figure 2). Multiple biopsies revealed persistent malignant cells, which led to the decision to proceed with photodynamic therapy for the residual disease.

See important prescribing and safety information for PHOTOFRIN® (porfimer sodium) for Injection on pages 3 and 4.

The patient was administered the standard 2 mg/kg of PHOTOFRIN® intravenously and 48 hours later underwent upper GI endoscopy. Using a 2.5-cm diffusing fiber, the distal esophagus/GE junction region was treated in two segments at the energy setting of 300 Joules/cm, with a nominal wavelength of 630 nm ± 3 nm. Forty-eight hours later, the treated region had a response with significantly sloughing mucosa (Figure 3).

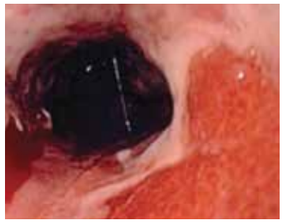

Figure 2 – Nodular patches in distal esophagus.

Figure 3 – Sloughing mucosa post PHOTOFRIN® treatment.

Clinical Outcomes

Subsequent to the multimodality treatment, the patient developed symptoms of dysphagia, secondary to esophageal stricture formation, which was treated with sequential endoscopic dilation procedures in the outpatient setting. After alleviation of the stricture, the patient continued to be surveyed (Figure 4). He remained cancer free until his demise, secondary to a cardiac event.

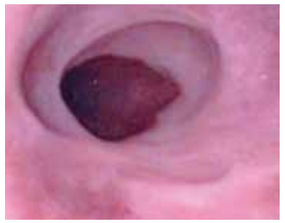

Figure 4 – Endoscopy 3 years post PHOTOFRIN® treatment.

Discussion

This case provides a demonstration of multimodal treatment in esophageal cancer where mere endoscopic resection or chemotherapeutic modality was inadequate. Additional local treatment with photodynamic therapy resulted in alleviation of cancer in an otherwise nonsurgical candidate. Adequate patient selection is a critical step to help achieve the best patient outcome.

The information contained in this case study has been supplied by the medical professional whose name appears here. The advice, opinion, statements, materials and other information expressed and contained in this case study are from the authors and reflect their personal experience with the specific patient. Results may vary. Pinnacle Biologics, Inc. makes no claim that similar treatment will result in a similar outcome.

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PHOTOFRIN® (porfimer sodium) for Injection Indications

Palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy.

Treatment of microinvasive endobronchial non–small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated.

Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC.

Ablation of high-grade dysplasia (HGD) in Barrett's esophagus (BE) patients who do not undergo esophagectomy.

Important Safety Information About PHOTOFRIN® (porfimer sodium) for Injection

PHOTOFRIN® should not be used in patients with porphyria, existing tracheoesophageal or bronchoesophageal fistula, tumors eroding into a major blood vessel, emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection of PHOTOFRIN® and laser light treatment, and esophageal or gastric varices or esophageal ulcers >1 cm in diameter.

IMPORTANT WARNINGS AND PRECAUTIONS USING PHOTOFRIN® INCLUDE:
Gastroesophageal Fistula and Perforation: Do not initiate PHOTOFRIN with photodynamic therapy (PDT) in patients with esophageal tumors eroding into the trachea or bronchial tree or bronchial wall.
Pulmonary and Gastroesophageal Hemorrhage: Assess patients for tumors eroding into a pulmonary blood vessel and esophageal varices. Do not administer light directly to an area with esophageal varices.
High-Grade Dysplasia (HGD) in Barrett's Esophagus (BE): After treatment of HGD in BE, conduct endoscopic biopsy surveillance every 3 months, until 4 consecutive negative evaluations for HGD have been recorded.
Photosensitivity and Ocular Photosensitivity: Observe precautions to avoid exposure of skin and eyes to direct sunlight or bright indoor light for at least 30 days. Instruct patients when outdoors to wear dark sunglasses which have an average light transmittance of <4% for at least 30 days and until ocular sensitivity resolves.
Use Before or After Radiotherapy: Allow 2-4 weeks between PDT and subsequent radiotherapy.
Chest Pain: Substernal chest pain can occur.
Airway Obstruction and Respiratory Distress: Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Monitor patients closely between the laser light therapy and the mandatory debridement bronchoscopy for any evidence of respiratory distress.
Esophageal Strictures: Esophageal strictures can occur.
Hepatic and Renal Impairment: Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity.
Thromboembolism: Thromboembolic events can occur.
Embryo-Fetal Toxicity: May cause embryo-fetal toxicity. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

MOST COMMON ADVERSE REACTIONS reported during clinical trials (>10% of patients) are:

Esophageal Cancer: Anemia, pleural effusion, pyrexia, constipation, nausea, chest pain, pain, abdominal pain, dyspnea, photosensitivity reaction, pneumonia, vomiting, insomnia, back pain, pharyngitis.