

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.

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**.

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Advanced Obstructing, Bleeding Esophageal Adenocarcinoma

Courtesy of Omar Awais, MD

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Patient History

This 73-year-old female complained of worsening heartburn and dysphagia with both solid and soft foods for a period of three to four months. Additionally, she was admitted to a local hospital with recent 13-pound weight loss and anemia. The patient had a history of hypertension, Chronic obstructive pulmonary disease (COPD), hyperlipidemia, depression, and Gastroesophageal reflux disease (GERD), and smoked two packs of cigarettes per day for the past 60 years. She did not use alcohol.

Examination

The patient presented with stable vital signs and a body mass index of 28 kg/m². She was clinically well and in no acute distress. Upon examination she had no palpable adenopathy, a soft abdomen, and normal neurologic and pulmonary exam.

Diagnostic Evaluation

Initial Esophagogastroduodenoscopy (EGD) examination revealed a partial obstructing bleeding esophageal tumor from 30-34, with extension to the gastric cardia. A moderate-sized hiatal hernia was also observed. Positron Emission Tomography – Computed Tomography (PET/CT) showed multiple lung masses:

1. A 6.3 x 6.1 cm mass in the posterior right lower lung with a Standardized Uptake Value (SUV) of 7.9 and extension to the right posterior pleural surface
2. A 2.66 x 2.1 cm mass in the superior segment left lower lung with an SUV of 3.5
3. A 1.2 cm mass in the upper lung with an SUV of 4.5
4. A 1.6 x 1.7 cm mass in the right lower lung with an SUV of 5.5
5. A 5 x 3.7 cm mass in distal esophagus extending into the fundus of the stomach with an SUV of 7.0

The PET/CT prompted additional biopsy of large right lung mass which were also positive for a second primary non-small cell lung carcinoma (NSCLC). There was no evidence of liver, adrenal, or osseous metastases.

Pulmonary function tests were poor, with an Forced expiratory volume (FEV) of 69-73% and a Diffusion lung capacity for carbon monoxide (DLCO) of 35% (Figure 1).

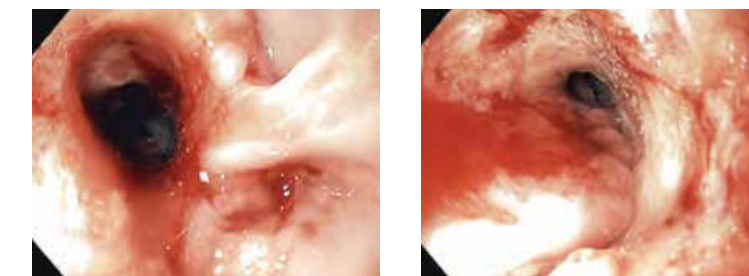


Figure 1 – Endoscopy before PHOTOFRIN® (porfimer sodium) for Injection treatment

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

Course of Treatment

During clinical staging, the patient was diagnosed with a bleeding, obstructing esophageal mass and a separate advanced lung primary. In the opinion of the treating physician, the patient could not be satisfactorily treated with Nd:YAG laser therapy. The patient was given PDT as a local modality to help improve her dysphagia and to control bleeding prior to initiating systemic therapy. The standard 2 mg/kg of PHOTOFRIN® (porfimer sodium) for Injection was administered intravenously. Forty-eight hours later, using a 5 cm diffusing fiber, the near obstruction bleeding distal esophageal tumor was treated at the energy setting of 300 Joules/cm² for 12.5 minutes with a nominal wavelength of 630 nm ± 3 nm. The same location was re-treated at 300 Joules/cm² two days later and the patient was discharged with a stable hemoglobin tolerating a soft diet (Figure 2).

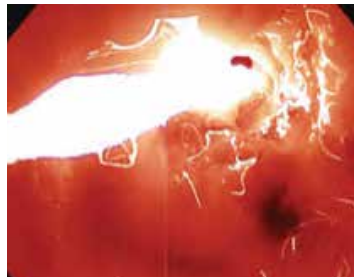


Figure 2 – Endoscopy during PHOTOFRIN® (porfimer sodium) for Injection administration.

Clinical Outcomes

During clinical follow-up two weeks after PDT treatment, the patient reported that her dysphagia was markedly improved (Figure 3). She was able to tolerate soft and hard solids without any difficulty and did not require the need for enteral access for nutritional supplementation. In addition, her hemoglobin and hematocrit was stable. The patient was subsequently referred to medical oncology for systemic treatment of her esophageal and lung carcinoma.



Figure 3 – Endoscopy after PHOTOFRIN® (porfimer sodium).

Discussion

This case provides a good demonstration of how PDT can be used as a local modality for advanced esophageal cancer. As in this patient, PDT can serve as a bridge to eventual definitive or palliative systemic therapy. Local treatment with PDT resulted in significant improvement in dysphagia and control of bleeding, and avoided a feeding tube in an otherwise nonsurgical candidate. Improvement of dysphagia and control of bleeding from both an obstructing and friable tumor is fairly rapid with PDT. This allows the patient to resume adequate oral intake to remain nutritionally sound. Proper patient selection is a critical step to help achieve optimal patient outcome.

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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.

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.