

PHOTOFRIN® (porfimer sodium) for Injection

CASE STUDY: Management of Locally Advanced Non–Small Cell Cancer With Central Airway Obstruction: A Multimodality Approach

Courtesy of Omar Awais, MD
Chief of Thoracic Surgery, Mercy Hospital
University of Pittsburgh Medical Center

PHOTOFRIN® (porfimer sodium) IS INDICATED FOR

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.

PHOTOFRIN® (porfimer sodium) is indicated for the ablation of high-grade dysplasia (HGD) in Barrett's esophagus patients who do not undergo esophagectomy.

IMPORTANT SAFETY INFORMATION ABOUT PHOTOFRIN FOR INJECTION

Photodynamic therapy (PDT) with PHOTOFRIN is a two-stage process requiring administration of both drug and light in a properly equipped facility. Refer to the OPTIGUIDE™ instructions for use for complete instructions concerning the fiber optic diffuser.

PHOTOFRIN is contraindicated in patients with porphyria. PDT is contraindicated in patients with an existing tracheoesophageal or bronchoesophageal fistula and patients with tumors eroding into a major blood vessel. PDT is not suitable for emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection with PHOTOFRIN and laser light treatment. PDT is not suitable for patients with esophageal or gastric varices, or patients with esophageal ulcers >1 cm in diameter. Tracheoesophageal or bronchoesophageal fistula can occur if esophageal tumor is eroding into trachea or bronchial tree. Gastrointestinal perforation can occur. There is a high risk of bleeding in patients with esophageal varices and for fatal massive hemoptysis with endobronchial tumors that are: large, centrally located; cavitating; extensive, extrinsic to the bronchus. After treatment of high-grade dysplasia (HGD) in Barrett's esophagus (BE), monitor endoscopic biopsy every three months, until four consecutive negative evaluations for HGD have been recorded. Photosensitivity can be expected; ocular sensitivity is possible. Allow 2-4 weeks between PDT and subsequent radiotherapy. Substernal chest pain may occur after treatment. Treatment-induced inflammation can cause airway obstruction. Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Esophageal stenosis occurs frequently after treatment of HGD in BE. Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity (possibly more than 90 days). Thromboembolic events can occur following photodynamic therapy with PHOTOFRIN.

MOST COMMON ADVERSE REACTIONS reported during clinical trials 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.

Inform patients to report adverse reactions. All patients who receive PHOTOFRIN will be photosensitive for at least 30 days and should be warned about this and counselled to take appropriate precautions. Laser treatment should not be given if an overdose of PHOTOFRIN is administered.

FOR MORE INFORMATION ABOUT PHOTOFRIN visit www.Photofrin.com or call Concordia Laboratories Inc. at 1-877-370-1142.

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.

Please see full prescribing information for PHOTOFRIN.



PATIENT HISTORY

This 56-year-old female presented with a history of worsening dysphagia, shortness of breath, hemoptysis, and right arm pain radiating to the back. Her medical history was significant for smoking (approximately 30 packs/year), asthma, hepatitis C carrier, carpal tunnel syndrome, depression, urinary incontinence, esophageal stricture, duodenal ulcer, and chronic obstructive pulmonary disease (COPD).

EXAMINATION

The patient had stable vital signs and was in no acute distress. Her dyspnea was considerable with exertion and activity. On examination, she had no palpable adenopathy, but she did have decreased breath sounds in the right lung fields.

DIAGNOSTIC EVALUATION

A computed tomography (CT) scan of the chest showed a large, poorly characterized mass in the right hilum with invasion into the right main stem bronchus and its segments. The CT scan also showed subsequent collapse of the right upper lobe and partial collapse of the right middle lobe with evidence of invasion into the mediastinum and first rib. The patient underwent a bronchoscopy with biopsy of endobronchial mass and YAG laser for ablation of the tumor.

Pathology confirmed non-small cell squamous cell carcinoma, while bronchoscopy revealed endobronchial tumor obstructing the proximal right main bronchus and bronchus intermedius with obstruction of right upper-lobe orifice (Figure 1, left). The middle lobe, lower lobe, basilar segments, and superior segment were patent. Chest radiography confirmed right lung collapse due to obstructing tumor (Figure 1, right).

BRONCHOSCOPY POST YAG LASER/RADIOGRAPH

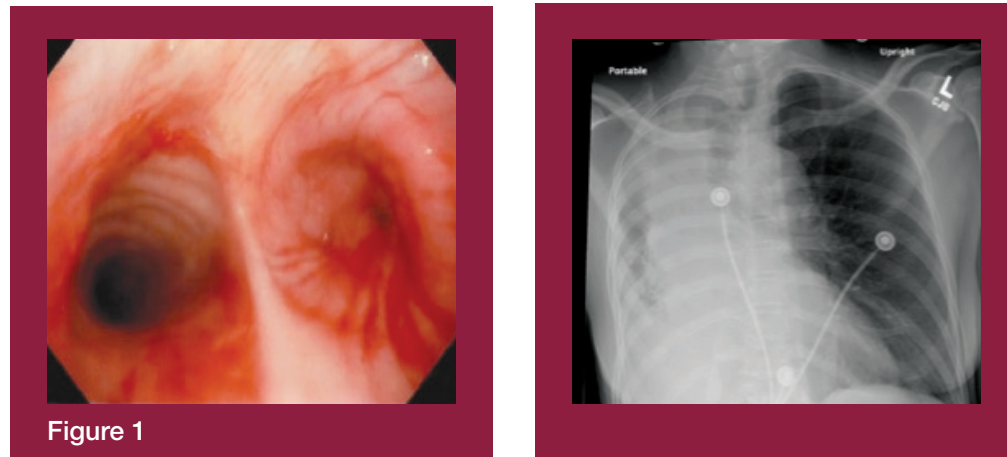


Figure 1 Bronchoscopy after YAG laser (left) and chest X-ray (right).

COURSE OF TREATMENT

Because of the patient's comorbidities and obstructing endobronchial disease, patient was offered photodynamic therapy (PDT) as a local modality to help improve her shortness of breath prior to initiating palliative chemoradiation therapy. The patient was administered the standard 2 mg/kg dose of PHOTOFRIN® (porfimer sodium) intravenously. Forty-eight hours later, the obstructing tumor within the bronchus intermedius and the right upper lobe bronchus was treated using a 2.5-cm diffusing fiber at the energy setting of 200 Joules/cm for a total of 8 minutes with a nominal wavelength of 630 nm \pm 3 nm. Two days later, the same location was retreated at 100 Joules/cm (Figure 2). Between treatments, the patient underwent endobronchial debriement of the tumor. Two days after the second treatment, the patient underwent placement of an AERO® fully covered 2-cm long, 12-mm diameter endoluminal airway stent.

IMAGE DURING PDT

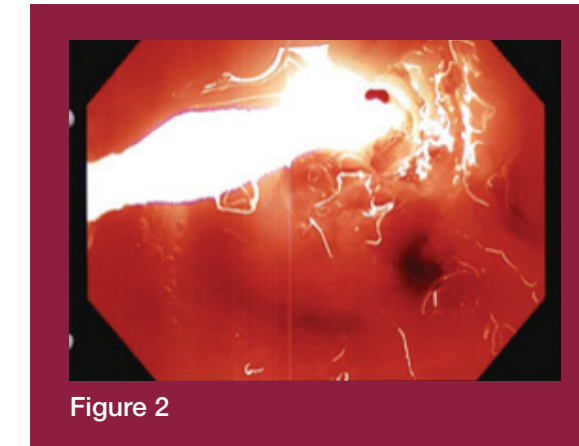


Figure 2 Bronchoscopy during PHOTOFRIN® (porfimer sodium) treatment.

CLINICAL OUTCOMES

After treatment with YAG laser, PHOTOFRIN® (porfimer sodium), and endobronchial stent, the patient reported during clinical follow-up that her dyspnea was markedly improved, and her oxygen requirements came down from 8 L to 2 L. She was discharged and eventually received palliative chemoradiation therapy. Figure 3 shows bronchoscopy and chest X-ray post PHOTOFRIN treatment. Figure 4 shows bronchoscopy and chest X-ray post stent placement.

BRONCHOSCOPY POST PDT

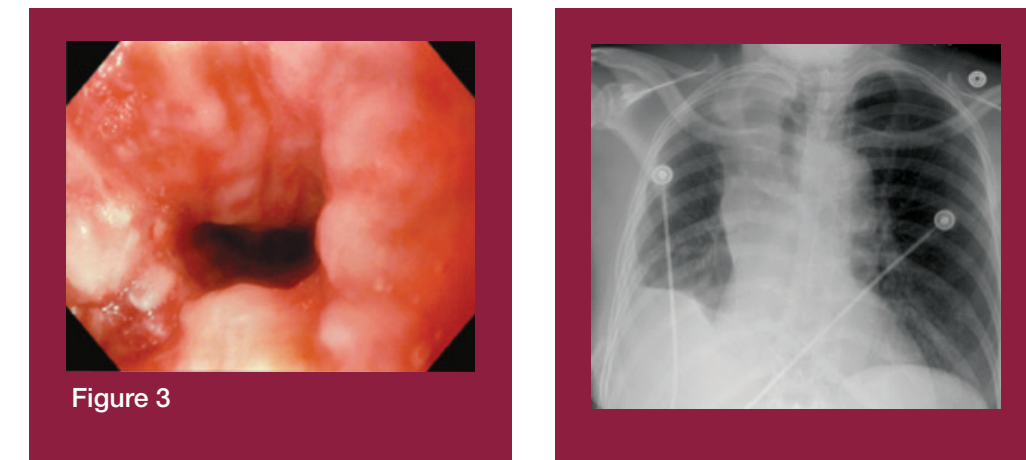


Figure 3 Bronchoscopy (left) and chest X-ray (right) post PDT treatment with PHOTOFRIN.

IMAGES AFTER STENT PLACEMENT



Figure 4 Bronchoscopy (left) and chest X-ray (right) post stent placement.

DISCUSSION

This case provides a good demonstration of how YAG laser, PHOTOFRIN® (porfimer sodium) treatment, and endoluminal stent placement can be used as a local multimodality therapy for advanced endobronchial lung cancer. As was the case with this patient, PDT with PHOTOFRIN, can serve as a bridge to eventual definitive or palliative systemic therapy. Combined localized treatment resulted in removal of endobronchial obstruction and significant improvement in shortness of breath in an otherwise nonsurgical candidate. Proper patient selection is a critical step to help achieve optimal patient outcome.

The light dosimetry settings, in this case, may not be consistent with the PHOTOFRIN prescribing information.

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.

Please see accompanying Important Safety Information within sales aid and full Prescribing Information for PHOTOFRIN® (porfimer sodium).

FOR MORE INFORMATION ABOUT PHOTOFRIN visit www.Photofrin.com or call Concordia Laboratories Inc. at 1-877-370-1142.

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.

PHOTOFRIN® (porfimer sodium) and OPTIGUIDE™ are registered trademarks of Concordia Laboratories Inc. Pinnacle Biologics™ and the logo of Pinnacle Biologics™ are trademarks of Pinnacle Biologics, Inc. PHOTOFRIN® is manufactured by Jubilant Hollisterstier General Partnership for Concordia Laboratories Inc. and distributed in the United States by Pinnacle Biologics, Inc.

Concordia Laboratories Inc. St. Michael, Barbados BB11005

See more at: <http://www.photofrin.com/healthcare-professional-home/#sthash.FlnUv0e7.dpuf>.

If there are any questions regarding the information provided, please contact Concordia's Medical Information Department at 1-877-370-1142.

