

**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.

**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](http://www.photofrin.com)**

**FOR MORE INFORMATION** about PHOTOFRIN®, or if there are any questions regarding the information provided, visit [www.photofrin.com](http://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](http://www.fda.gov/medwatch), or call **1-800-FDA-1088**.

PHOTOFRIN® 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 distributed in the United States by Pinnacle Biologics, Inc., Bannockburn, IL 60015

ADP-040 08/2020  
All rights reserved.

# 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

## 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 - A). The middle lobe, lower lobe, basilar segments, and superior segment were patent. Chest radiography confirmed right lung collapse due to obstructing tumor (Figure 1 - B).

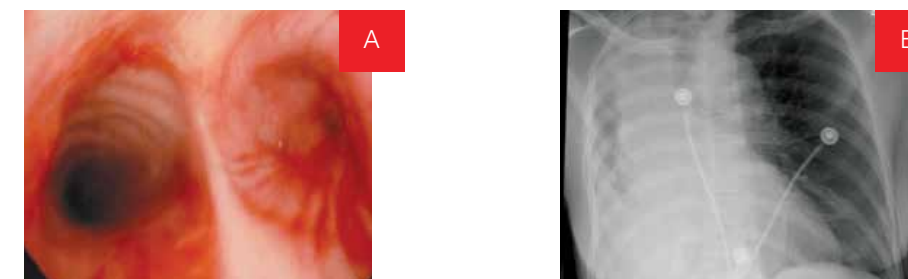


Figure 1 – A) Bronchoscopy after YAG laser and B) Chest X-ray

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

## 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) for Injection 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 ±3 nm. Two days later, the same location was retreated at 100 Joules/cm (Figure 2). Between treatments, the patient underwent endobronchial debridement 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.

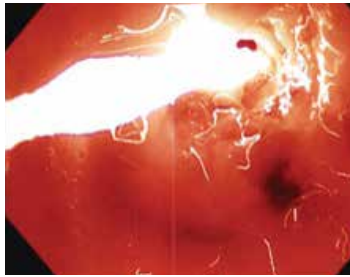


Figure 2 – Bronchoscopy during PHOTOFRIN® (porfimer sodium) for Injection treatment.

## Clinical Outcomes

After treatment with YAG laser, PHOTOFRIN® (porfimer sodium) for Injection, 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.

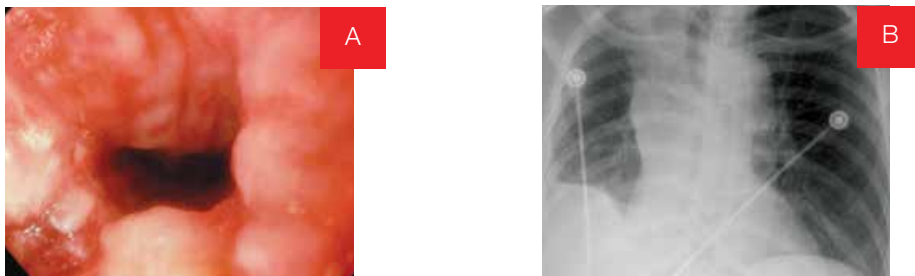


Figure 3 – Figure 3 - A) Bronchoscopy and B) Chest X-ray post PDT treatment with PHOTOFRIN® (porfimer sodium) for Injection.

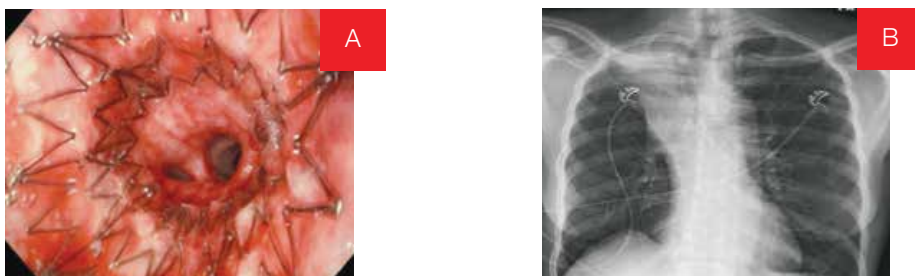


Figure 4 – A) Bronchoscopy and B) Chest X-ray post stent placement

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

## 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 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.