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.
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-035 08/2020

PDT with PHOTOFRIN® [porfimer sodium] for injection

PINNACLE BIOLOGICS™

Non-operative obstructive squamous cell carcinoma of the right lower lobe bronchus

Courtesy of Harmik J. Soukiasian, MD, FACS
Chief, Division of Thoracic Surgery
Cedars-Sinai Medical Center

Patient History

This 58-year-old female presented with multiple comorbidities significant for coronary artery disease, a history of myocardial infarction status post coronary artery bypass graft (CABG), multiple stents, and severe chronic obstructive pulmonary disease (COPD). She had initially been admitted for pneumonia and was later found to have a large obstructive lesion in the right bronchus intermedius that was biopsied as squamous cell carcinoma upon bronchoscopy. Her workup included PET scan, brain scan, and endobronchial ultrasound (EBUS), which showed a negative mediastinum.

The patient was deemed a poor surgical candidate because of her diffusing capacity of the lungs for carbon monoxide (DLCO) of 32%. She continued to have shortness of breath despite receiving IV antibiotics for her pneumonia, likely secondary to her obstructive lesion. She was deemed an appropriate candidate for photodynamic therapy (PDT).

Examination

Physical examination revealed stable vital signs with no acute distress; however, she became short of breath with conversation. She was obese and appeared older than her stated age. Upon further examination, she had rhonchi and decreased breath sounds on the right, and a soft abdomen, yet cardiopulmonary exam was unremarkable.

Diagnostic Evaluation

A CT scan revealed near-total atelectasis of the right lower lobe due to obstruction of the right lower lobe bronchus. Small scattered pulmonary nodules were present, many of which were new or increased in size. Bronchoscopy with EBUS was performed to evaluate the mediastinal lymph nodes and obtain a tissue biopsy of the endobronchial lesion. The scope was sequentially passed into the left main bronchi, followed by the left upper and lower bronchi. The scope was subsequently advanced into the right main bronchus and then the right upper lobe (RUL), and bronchus intermedius.

There was a necrotic endobronchial lesion completely obstructing the entrance to the right middle lobe (RML) and right lower lobe (RLL) in the distal bronchus intermedius (Figure 1). The bronchoscope was then switched into EBUS bronchoscope and 7 endobronchial fine needle aspiration (FNA) biopsies were obtained from mediastinal lymph node stations 4R and 10R. These lymph node stations were negative for carcinoma, but chest radiograph confirmed right lower lobe collapse (Figure 1).

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

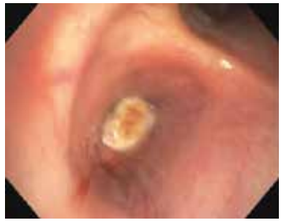
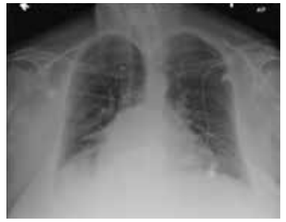

Figure 1 – Bronchoscopy (left) and radiography (right) pre-PDT with PHOTOFRIN® (porfimer sodium) for Injection.

Course of Treatment

Due to the patient's significant cardiac comorbidities and poor pulmonary function, she was offered photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for Injection as a local modality to help improve shortness of breath prior to initiating definitive chemoradiation therapy. The patient received the standard 2 mg/kg of PHOTOFRIN® intravenously. Forty-eight hours later, a 2.5-cm diffusing fiber was used to treat the obstructing tumor within the right bronchus intermedius at the energy setting of 200 Joules/cm for a total of 8 minutes with a wavelength of 630 nm ±3 nm (Figure 2). Two days later, the same location was re-treated at 200 Joules/cm. Between light applications, the patient underwent endobronchial debridement of tumor.

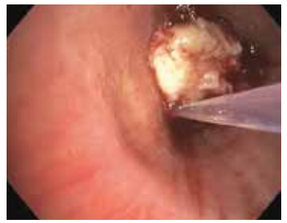

Figure 2 – Bronchoscopy with catheter during first PHOTOFRIN® (porfimer sodium) for injection treatment.

Clinical Outcomes

After her second light treatment and debridement, the patient began to notice an improvement in her breathing. Her oxygen requirements improved and she was eventually discharged from the hospital. The bronchoscopic image (Figure 3) shows eradication of endobronchial tumor after completion of just 2 treatments. The radiograph (Figure 3) shows resolution of right lower lobe collapse post-treatment.

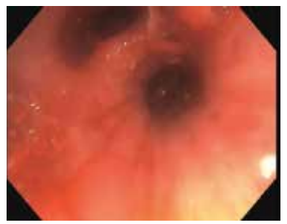
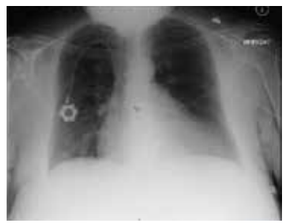

Figure 3 – Bronchoscopy (left) and radiography (right) post-PDT with PHOTOFRIN® (porfimer sodium) for Injection.

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

Discussion

This case study showcased a clinical scenario in which PDT with PHOTOFRIN® (porfimer sodium) for Injection can be used as a local modality for endobronchial lesions in the setting of lobar collapse and post-obstructive pneumonia. This is especially useful in patients who need to be optimized prior to surgery or those who are deemed nonsurgical candidates. It is important to ensure that there is good lung and open airways distal to the obstruction in these patients. Patient selection is the most important step in efficiently and effectively using PDT with PHOTOFRIN® (porfimer sodium) for Injection to achieve optimal patient outcomes.

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.