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**.

PDT with PHOTOFRIN® TARGETING ~~CANCER~~ ~~MARGINS~~ (porfimer sodium) for injection

PINNACLE BIOLOGICS™

Oligometastatic Recurrent Lung Adenocarcinoma in the Trachea

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Patient History

A 59-year-old male former smoker (140 pack-year history; quit in 2018) with a history of chronic obstructive pulmonary disease, pT1bN0M0 lung adenocarcinoma of the right upper lobe treated with lobectomy 2 years ago, and pT1cN0M0 lung adenocarcinoma of the lingula treated with wedge resection 10 months ago presented for further evaluation of hemoptysis and cough.

Examination

Physical examination was remarkable for decreased breath sounds bilaterally and well healed surgical scars. There was no stridor.

Diagnostic Evaluation

Computed tomography imaging of the chest demonstrated an infiltrate in the right middle lobe. A 1.0 cm endoluminal exophytic nodule on the lateral wall of the mid-trachea was incidentally identified during flexible bronchoscopy performed via a laryngeal mask airway. Biopsies of the nodule confirmed lung adenocarcinoma. Cultures from bronchoalveolar lavage of the right middle lobe were negative.

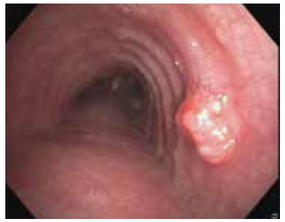

Figure 1A - Tracheal lesion pretreatment, September 2019

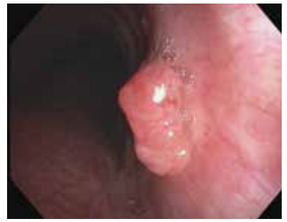

Figure 1B - Close-up of tracheal lesion pretreatment, September 2019

Course of Treatment

The case was discussed in a multidisciplinary conference (i.e. tumor board) with thoracic surgery, medical oncology, and radiation oncology. The consensus was to proceed with local treatment using photodynamic therapy. The patient received a 2mg/kg intravenous infusion of PHOTOFRIN® (porfimer sodium) for Injection followed by the initial illumination 72 hours later after the washout period.

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

As pictured below, a 1.0 cm rigid diffuser was positioned adjacent to the lesion for the first treatment.

Fiberoptic Diffuser Selection	
Fiber Type	Rigid Fiberoptic Diffuser
Fiber Length	1 cm
Fiber Placement	Adjacent Placement

Bronchoscopy & Light Application	
First Light Application, Total Dosimetry	200 J/cm x 500 seconds

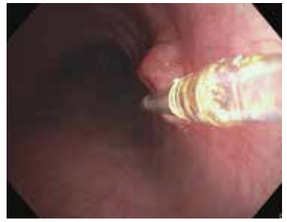

Figure 2 - Tracheal lesion during first PDT light activation, November 2019

As pictured below, a 1.5 cm rigid diffuser was positioned interstitially for the second treatment 2 days later.

Fiberoptic Diffuser Selection	
Fiber Type	Rigid Fiberoptic Diffuser
Fiber Length	1.5 cm
Fiber Placement	Interstitial Placement

Bronchoscopy & Light Application	
First Light Application, Total Dosimetry	200 J/cm x 500 seconds

Figure 3A - Tracheal lesion during second PDT light activation, November 2019

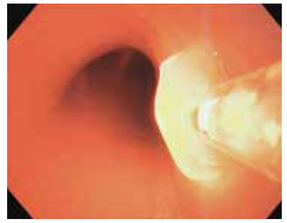

Figure 3B - Tracheal lesion during second PDT light activation, November 2019

Clinical Outcomes

There was no evidence of residual tumor on repeat airway examination with flexible bronchoscopy two months later. Biopsies confirmed the absence of microscopic disease. Repeat biopsies at 12 months were also negative. The patient avoided direct sunlight for 4 weeks after receiving the PHOTOFRIN® (porfimer sodium) for injection and had no adverse effects from the medication or treatment.

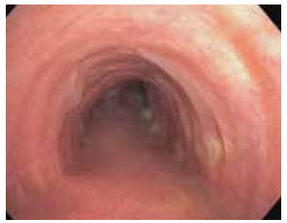

Figure 4A - Follow up bronchoscopy (2 months post PDT treatment), January 2020

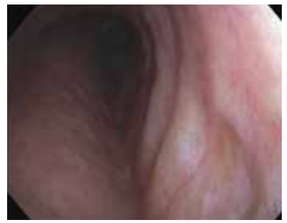

Figure 4B - Follow up bronchoscopy (12 months post PDT treatment), December 2020

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

Discussion

This case demonstrates the utility of photodynamic therapy for treatment of endobronchial tumors. It highlights the tolerability of this therapy and the durability of response.

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.