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-043 08/2020

PDT with PHOTOFRIN® [porfimer sodium] for injection

PINNACLE BIOLOGICS™

Endobronchial Non–Small Cell Lung Cancer

Courtesy of Adnan Majid, MD, FCCP
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Harvard Medical School
Boston, MA

Patient History

A 79-year-old male, former smoker of 30 packs per year, had a history of tonsillar carcinoma treated with external beam radiation 3 years prior; skin carcinoma treated with resection; and prostate carcinoma treated with a radical prostatectomy. The patient presented with progressive dyspnea on exertion, cough, and mild hemoptysis.

Examination

Physical exam was pertinent for mild right-sided wheeze.

Diagnostic Evaluation

Initial work-up included a chest computer tomography (CT) scan (Figure 1) and a flexible bronchoscopy (Figure 2), which revealed a partially obstructing endobronchial squamous cell carcinoma, which makes up a large percentage of non-small cell lung cancer (NSCLC). It involved the carina and right main stem bronchus.

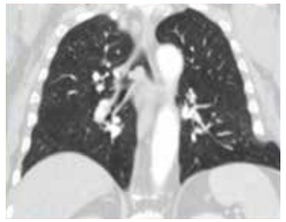

Figure 1 – Coronal view of the chest CT scan showing near complete obstruction of the right main stem bronchus.

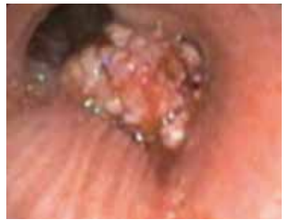

Figure 2 – Bronchoscopy showing friable tumor at the distal trachea with near complete obstruction of the right main stem bronchus.

Course of Treatment

The patient was evaluated by a multidisciplinary thoracic oncology group and the decision was made to proceed with an endobronchial intervention to relieve the obstruction. Given the location of the tumor, the patient received 2 mg/kg of PHOTOFRIN® intravenously at day 0. Two days later he was brought to the operating room where a flexible bronchoscopy was done under general anesthesia using a laryngeal mask. A 2.5-cm quartz diffusing fiber was introduced into the obstructing lesion in the right main stem bronchus and 200 Joules/cm of light were delivered, with a nominal wavelength of 630 nm ± 3nm.

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

Two days later, the patient underwent a rigid bronchoscopy and debridement of the necrotic tumor using a cryorecanalization technique. After removal of the necrotic tumor, there was minimal bleeding, which was controlled with electrocautery (Figure 3).

The patient was discharged and scheduled for further staging work-up, which included a brain magnetic resonance imaging (MRI), body fusion positron emission tomography (PET)/computer tomography scan, flexible bronchoscopy with linear endobronchial ultrasound (EBUS)/transbronchial needle aspiration (TBNA) of the mediastinum, and radial EBUS. Results were negative for local, regional, or distant metastatic disease, concluding that no further treatment was necessary.

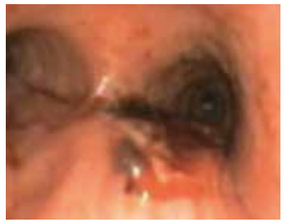

Figure 3 – Patient airway after cryodebridement and electrocautery.

Clinical Outcomes

The patient underwent endoluminal therapy, which provided symptomatic palliation. He receives annual follow-up with a fusion body PET/CT scan and flexible bronchoscopy without evidence of tumor recurrence (Figures 4, 5, and 6). Results may vary. Please see accompanying efficacy results from the PHOTOFRIN® clinical studies within sales aid for additional context.

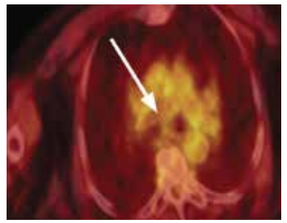

Figure 4 – PET scan (axial view) 1 year post PDT without evidence of local, regional, or distant metastatic disease.

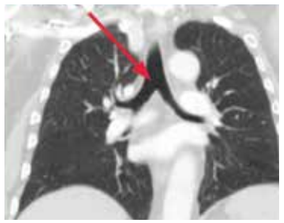

Figure 5 – Chest CT scan (coronal view) 1 year post PDT showing patient airways without evidence of local or regional tumor recurrence.

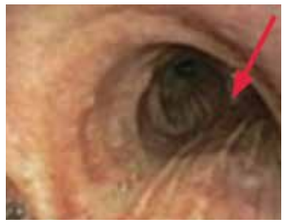

Figure 6 – Flexible bronchoscopy (white light imaging) 1 year post PDT without evidence of local recurrence.

Discussion

Photodynamic therapy in carefully selected patients can be used both for palliation and to help achieve a complete response in microinvasive endobronchial NSCLC. After recanalization of the airways, all patients should undergo complete staging work-up to further determine prognosis and treatment. In my patients who are being considered for endoscopic therapy with curative intent, staging with the use of radial EBUS has helped determine the degree of airway wall invasion and forecast success of local therapy.

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

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.