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-037 08/2020

Stage 3b Squamous Cell Cancer of the Lung

Courtesy of Christopher Parks, MD
Emory University Hospital and Cancer Treatment Centers of America – Atlanta, and Georgia Regents University

Patient History

This 63-year-old male had a 60 pack per year history of smoking. Having been diagnosed with squamous cell cancer of the lung, stage 3b, he initially received treatment with chemotherapy (paclitaxel and cisplatinum) and radiation. Within a year of diagnosis, he underwent a thoracotomy, which had to be aborted because of invasion of the mediastinum. He subsequently began chemotherapy with a combination of docetaxel, gemcitabine, and bevacizumab.)

Examination

Almost a year later, the patient arrived at our facility for a second opinion. At that time, he complained of shortness of breath with cough, but presented with no hemoptysis and physical exam was unremarkable. Bronchoscopy and PET scan were performed, revealing a lesion of 0.5-1.0 cm (Figures 1 and 2).

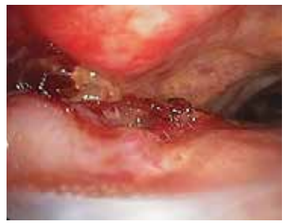

Figure 1 – Bronchoscopy revealing lesion.

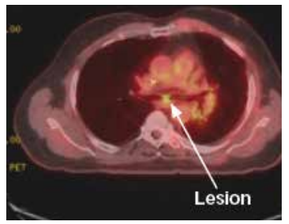

Figure 2 – PET scan revealing lesion.

Diagnostic Evaluation

A fungating mass was found protruding from the subcarinal space. With consultation from Radiology, it was determined that no further radiation was possible. Because Medical Oncology felt options were limited and Surgery deemed the patient to be inoperable, PDT with PHOTOFRIN® (porfimer sodium) for Injection was chosen.

Course of Treatment

The patient was administered the standard 2 mg/kg of PHOTOFRIN® (porfimer sodium) for Injection intravenously and 48 hours later underwent endoscopy. Using a 2.5 cm diffusing fiber placed bilaterally, the patient received a total of 200 Joules/cm^2 for 8 minutes 20 seconds to both the left and right of the carina, with a nominal wavelength of 630 nm ±3 nm. Repeat endoscopy with debridement was performed, as well as a second activation 2 days later. A final debridement was performed on day 7. Following PDT activation there was an inflammatory response (Figure 4), which improved over the next 3 months.

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

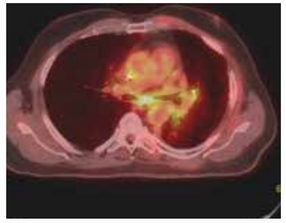

Figure 3 – PET scan. The expanded yellow area represents the temporary inflammatory response generated following PDT.

Figure 4 – Bronchoscopy showing inflammation, 7 days post-PHOTOFRIN ® treatment.

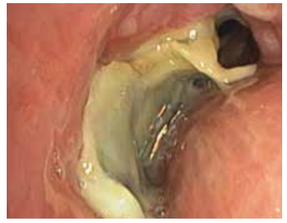

Figure 5 – Bronchoscopy 3 months post-PHOTOFRIN ® treatment.

Clinical Outcomes

At clinical follow-up, the patient reported significant improvement of his shortness of breath and coughing symptoms. One year post-PHOTOFRIN® (porfimer sodium) for Injection treatment, bronchoscopy and PET show no evidence of recurrence

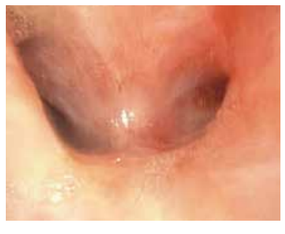

Figure 6 – Post-PHOTOFRIN ® treatment bronchoscopy.

Figure 7 – Post-PHOTOFRIN ® treatment PET scan. Notice that there is no lesion present at post-PDT 1 yr. follow-up either in the bilateral carina region or adjacent lymph node.

Discussion

Though we were initially concerned as to whether PDT could fully ablate the lesion that was 0.5-1.0 cm deep, the PDT ablation penetration was deeper than expected and we were able to clear the carina and the subcarinal space, providing excellent radiographic and symptomatic response. This case is an example of how PDT treatment with PHOTOFRIN gives patients another option when other modalities have been exhausted.

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.

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

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.

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.