

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**.

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Advanced Left Distal Main Stem Endobronchial Squamous Cell Carcinoma Tumor With Obstruction of Left Upper Lobe Bronchus

Courtesy of Omar Awais, MD

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Patient History

This 88-year-old male presented with worsening dyspnea over a couple of months. The patient's medical history was significant for chronic kidney disease requiring immunosuppression, CAD, HTN, anemia, GI bleed secondary to AVM, BPH, anxiety, and atrial fibrillation, as well as a 70 packs/year history of smoking.

Examination

The patient presented with stable vital signs and no acute distress, although he had significant dyspnea with exertion/activity. Upon examination, he had no palpable adenopathy and decreased breath sounds in the left lung fields.

Diagnostic Evaluation

The CT scan performed on the patient's chest showed an ovoid obstructive lesion measuring at least 1.6 cm x 2.5 cm within the left upper lobe bronchus encroaching into the left lower lobe bronchus, with associated left lung collapse. The patient underwent a bronchoscopy with brushings and multiple biopsies.

Pathology showed squamous cell carcinoma. Bronchoscopy revealed no disease of carina, while the trachea was normal. The right upper, middle, and lower lobe showed no endobronchial disease. Distal left main bronchus had a tumor with complete obstruction of left upper lobe and near complete obstruction of left lower lobe. Chest radiograph, in addition to bronchoscopic investigation, confirmed left lung collapse due to obstructing tumor (Figure 1).



Figure 1 – Bronchoscopy and radiography pre-PHOTOFRIN® (porfimer sodium) for Injection treatment.

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, he was offered PDT as a local modality to help improve his shortness of breath prior to initiating palliative radiation therapy.

The patient was administered the standard 2 mg/kg of PHOTOFRIN® (porfimer sodium) for Injection intravenously, and 48 hours later, using a 2.5 cm diffusing fiber, the obstructing tumor within the left distal main bronchus was treated at the energy setting of 200 Joules/cm² for a total of 8 minutes with a wavelength of 630 nm. The same location was re-treated at 200 Joules/cm² 2 days later (Figure 2). Between PDT treatments, patient underwent endobronchial debridement of tumor. The patient was discharged to a local facility.



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

Clinical Outcomes

At clinical follow-up, post-PDT treatment, the patient reported that his dyspnea was markedly improved. His oxygen requirements improved and he was discharged to the TCU for rehabilitation to receive palliative radiation therapy. The bronchoscopic image on the left of Figure 3 shows eradication of endobronchial tumor after completion of treatment; the radiograph on the right reveals lung expansion post-treatment.

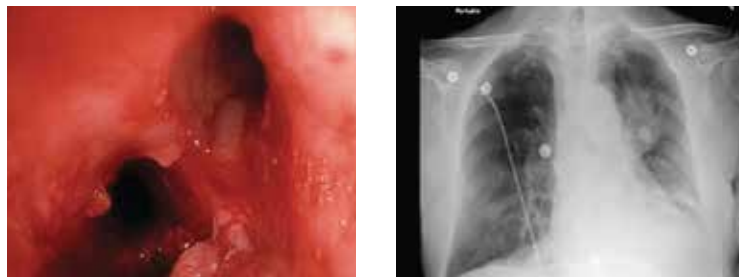


Figure 3 – Bronchoscopy and radiography post-PHOTOFRIN® (porfimer sodium) for Injection treatment.

Discussion

This case provides a good demonstration of how PDT can be used as a local modality for advanced endobronchial lung cancer when radiotherapy or surgery are not indicated at the time of PDT therapy. As it did with this patient, PDT can serve as a bridge to eventual definitive or palliative systemic therapy. Local treatment with PDT resulted in macroscopic eradication of endobronchial tumor and significant improvement in shortness of breath in an otherwise nonsurgical candidate. Proper patient selection is a critical step to help achieve an optimal patient outcome.

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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.