PHOTOFRIN® (porfimer sodium) for Injection

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

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PHOTOFRIN® (porfimer sodium) IS INDICATED FOR

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.

PHOTOFRIN® (porfimer sodium) is indicated for the ablation of high-grade dysplasia (HGD) in Barrett's esophagus patients who do not undergo esophagectomy.

IMPORTANT SAFETY INFORMATION ABOUT PHOTOFRIN FOR INJECTION

Photodynamic therapy (PDT) with PHOTOFRIN is a two-stage process requiring administration of both drug and light in a properly equipped facility. Refer to the OPTIGUIDE™ instructions for use for complete instructions concerning the fiber optic diffuser.

PHOTOFRIN is contraindicated in patients with porphyria. PDT is contraindicated in patients with an existing tracheoesophageal or bronchoesophageal fistula and patients with tumors eroding into a major blood vessel. PDT is not suitable for emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection with PHOTOFRIN and laser light treatment. PDT is not suitable for patients with esophageal or gastric varices, or patients with esophageal ulcers >1 cm in diameter.

Tracheoesophageal or bronchoesophageal fistula can occur if esophageal tumor is eroding into trachea or bronchial tree. Gastrointestinal perforation can occur. There is a high risk of bleeding in patients with esophageal varices and for fatal massive hemoptysis with endobronchial tumors that are: large, centrally located; cavitating; extensive, extrinsic to the bronchus. After treatment of high-grade dysplasia (HGD) in Barrett's esophagus (BE), monitor endoscopic biopsy every three months, until four consecutive negative evaluations for HGD have been recorded. Photosensitivity can be expected; ocular sensitivity is possible. Allow 2-4 weeks between PDT and subsequent radiotherapy. Substernal chest pain may occur after treatment. Treatment-induced inflammation can cause airway obstruction. Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Esophageal stenosis occurs frequently after treatment of HGD in BE. Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity (possibly more than 90 days). Thromboembolic events can occur following photodynamic therapy with PHOTOFRIN.

MOST COMMON ADVERSE REACTIONS reported during clinical trials 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.

Inform patients to report adverse reactions. All patients who receive PHOTOFRIN will be photosensitive for at least 30 days and should be warned about this and counselled to take appropriate precautions. Laser treatment should not be given if an overdose of PHOTOFRIN is administered.

FOR MORE INFORMATION ABOUT PHOTOFRIN visit www.Photofrin.com or call Concordia Laboratories Inc. at 1-866-248-2039. 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.

Please see full prescribing information for PHOTOFRIN.

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 pack 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).

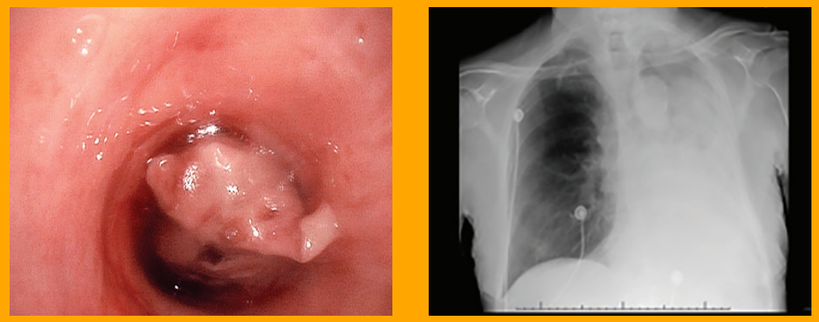

Figure 1

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

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) 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/cm^2 for a total of 8 minutes with a wavelength of 630 nm. The same location was re-treated at 200 Joules/cm^2 2 days later (Figure 2). Between PDT treatments, patient underwent endobronchial debridement of tumor. The patient was discharged to a local facility.

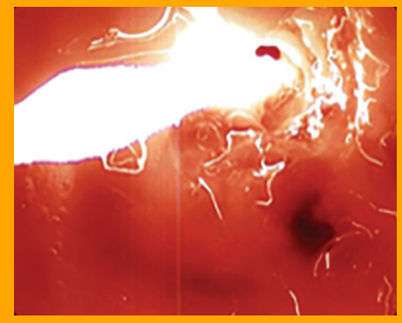

Figure 2

Figure 2 Bronchoscopy during PHOTOFRIN® (porfimer sodium) 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.

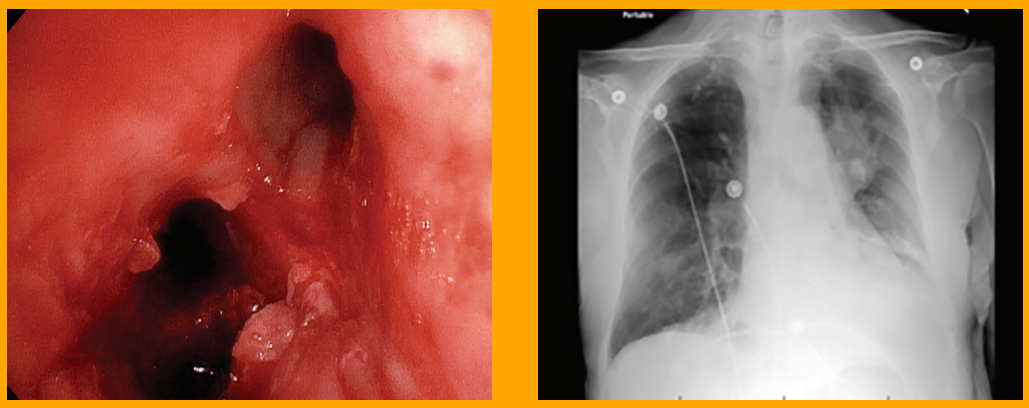

Figure 3

Figure 3 Bronchoscopy and radiography post-PHOTOFRIN® (porfimer sodium) 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.