PHOTOFRIN® (porfimer sodium) for Injection

CASE STUDY: Adenocarcinoma Consistent With Recurrent Lung Cancer

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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 1-877-370-1142.

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

Sixty-eight-year-old male with a history of lung cancer, coronary artery disease (CAD), hoarseness, and neuropathy underwent a right video-assisted thoracoscopic surgery (VATS) with subsequent conversion to thoracotomy and lower lobectomy, upper lobe wedge, and bronchoplasty for non–small cell adenocarcinoma of the lung. After one year, the patient developed consolidation and narrowing of the right mainstem bronchus and subsequently presented with persistent hemoptysis and dyspnea and was admitted to a local hospital.

EXAMINATION

Physical examination showed stable vital signs, although tachypnea was present. While the patient had no lymphadenopathy, inspiratory and expiratory stridor was present. Bronchoscopy revealed endobronchial obstruction and extraluminal compression, and pathology indicated recurrent adenocarcinoma.

DIAGNOSTIC EVALUATION

A CT scan of the chest showed a large right hilar mass with invasion into the right mainstem bronchus with near-complete obstruction. Additionally, a significant number of bilateral lung metastases were present. A biopsy was performed, and pathology confirmed adenocarcinoma consistent with recurrent lung cancer.

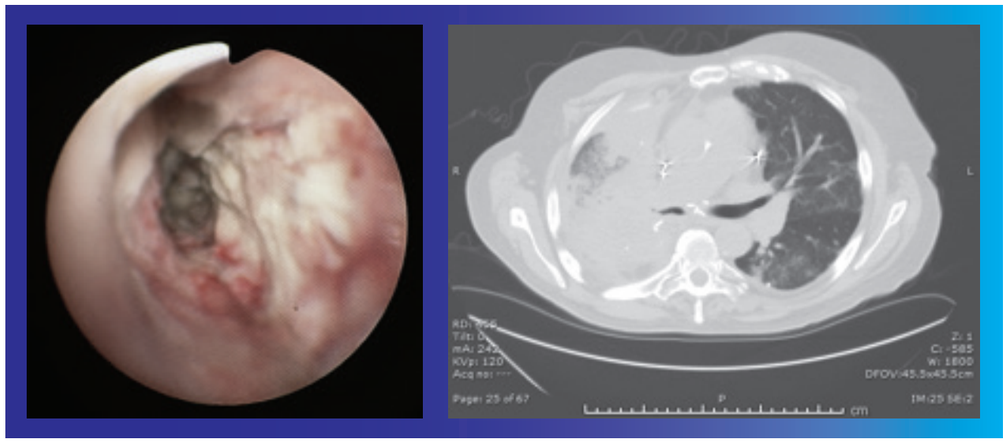

Figure 1. Bronchoscopy (left) and chest CT (right) pretreatment.

COURSE OF TREATMENT

Because of the patient's highly obstructing endobronchial lesion and prior cryoablation failure, he was offered photodynamic therapy (PDT). He received a 2 mg/kg IV infusion of PHOTOFRIN® (porfimer sodium) for Injection. Forty-eight hours later, the obstructing tumor within the right mainstem bronchus was treated using a 5-cm diffusing fiber at an energy setting of 200 Joules/cm for a total of 8 minutes and 20 seconds for a nominal wavelength of 630 nm ±3 nm (Figure 2). Two days later, the patient underwent a bronchoscopy in which the tumor in the right mainstem bronchus was debrided. The right mainstem was 100% patent.

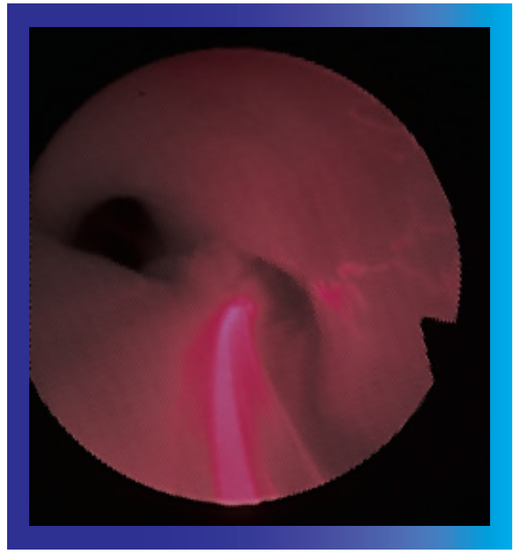

Figure 2. Bronchoscopy with catheter during PHOTOFRIN® (porfimer sodium) for Injection treatment.

CLINICAL OUTCOMES

After photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for Injection to the right mainstem bronchus, the patient reported at time of discharge that his dyspnea had markedly improved, and additional oxygen requirements were no longer needed. The bronchoscopic image (Figure 3) shows eradication of the tumor.

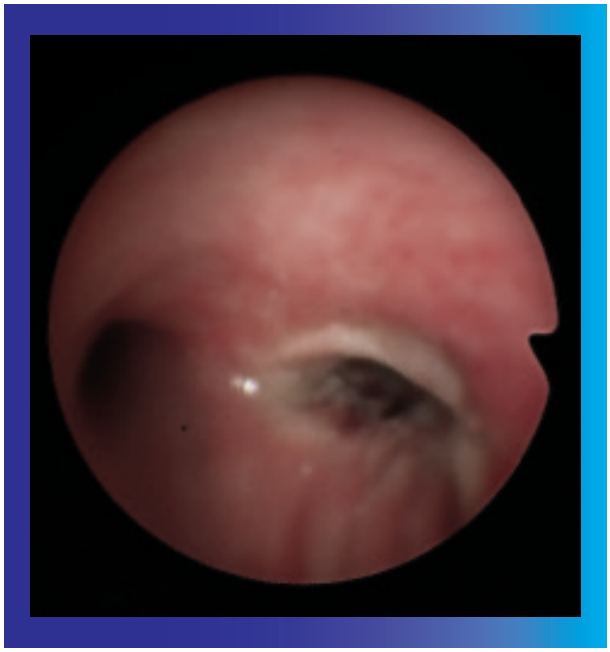

Figure 3. Bronchoscopy post-debridement and PDT with PHOTOFRIN® (porfimer sodium) for Injection.

DISCUSSION

This case study demonstrates a clinical scenario in which PDT with PHOTOFRIN can be used as a local modality for advanced lung cancer with endobronchial involvement where radiation or surgery has a limited role. PDT with PHOTOFRIN resulted in macroscopic eradication of endobronchial tumor with significant improvement in shortness of breath in a nonsurgical candidate. Proper patient selection is crucial to obtain the best clinical outcome.

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.

Please see accompanying Important Safety Information within sales aid and full Prescribing Information for PHOTOFRIN® (porfimer sodium).

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Concordia Laboratories Inc. St. Michael, Barbados BB11005

See more at: http://www.photofrin.com/healthcare-professional-home/#sthash.FlnUv0e7.dpuf.

If there are any questions regarding the information provided, please contact Concordia's Medical Information Department at 1-877-370-1142.

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PDT WITH PHOTOFRIN® (porfimer sodium) for Injection

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