PHOTOFRIN® (porfimer sodium) for Injection

CASE STUDY: 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

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 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 at a depth of 0.5-1.0 cm (Figures 1 and 2). The subcarinal lymph node was also found to be cancer positive.

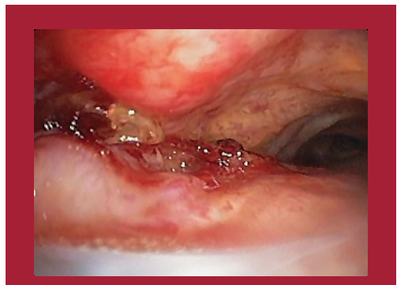

Figure 1

Figure 1 Bronchoscopy revealing lesion.

Figure 2

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) was chosen.

COURSE OF TREATMENT

The patient was administered the standard 2 mg/kg of PHOTOFRIN® (porfimer sodium) 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.

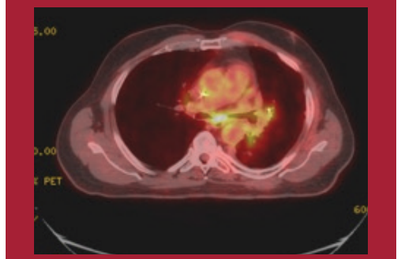

Figure 3

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

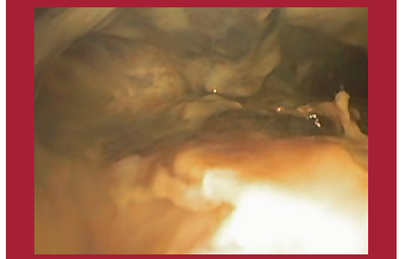

Figure 4

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

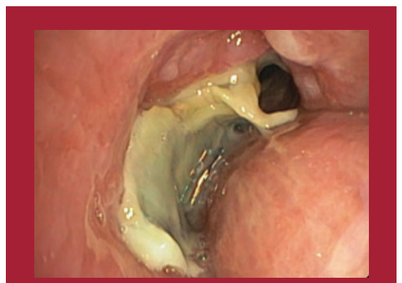

Figure 5

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) treatment, bronchoscopy and PET show no evidence of recurrence (see Figures 6 and 7).

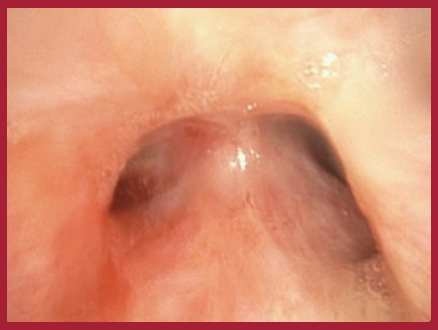

Figure 6

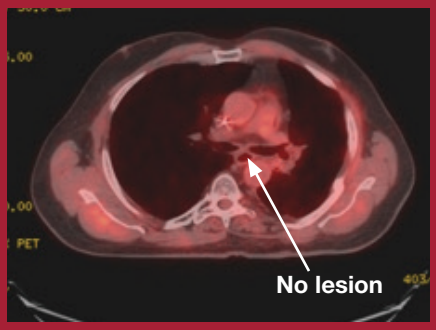

Figure 7

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.

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

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See more at: http://www.photofrin.com/healthcare-professional-home/#sthash.FInUv0e7.dpuf.

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PINNACLE BIOLOGICS