

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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Endobronchial Non–small Cell Lung Cancer

Courtesy of Wilson Tsai, MD

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Patient History

A 65-year-old male was diagnosed with stage 3B endobronchial non–small cell lung cancer (NSCLC) four years ago. He had a 50 packs/year smoking history, COPD, and complained of right anterior chest pain. A CT of the chest revealed a large right paratracheal mass with compressive effects on the SVC and encroachment, but not eroding into the pulmonary artery. A CT-guided biopsy of the right lung mass confirmed NSCLC. The patient underwent treatment with carboplatin and gemcitabine, then developed hemoptysis, dyspnea, and persistent cough.

Examination

Upon examination, it was determined the patient was not a surgical candidate due to the significant hemoptysis, dyspnea, and persistent cough. Endoluminal treatment was scheduled for his occlusive cancer and persistent symptoms.

Diagnostic Evaluation

Pulmonologist evaluation of the patient with a flexible bronchoscopy revealed a completely occluded right upper lobe, endobronchial NSCLC cancer with significant hemoptysis. Patient was referred for photodynamic therapy (PDT) (Figure 1).

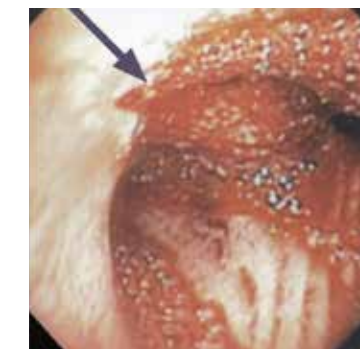


Figure 1 – Preliminary bronchoscope.

Course of Treatment

The patient underwent his initial PDT treatment, which revealed the tumor extended down to the bronchus intermedius (Figure 2). The tumor was noninclusive and proximally up to the carina. The patient received 500 seconds of PDT using a 1.5-cm DCYL 215 fiber at 200 Joules with a nominal wavelength of 630 nm ± 3 nm, without complications.

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

Findings during his follow-up PDT treatment were consistent with obstructive RUL endobronchial cancer with significant improvement of hemoptysis. Necrotic tumor was debried and the distal opening of the RUL was visualized (Figure 3).

At his third bronchoscopic follow-up, debridement of the entire tumor in the RUL orifice was performed, immediately followed by the final PDT treatment (Figure 4). The patient was discharged and developed a fever of 102°F one week later. He started antibiotics and acetaminophen, but his fever persisted. He was admitted to hospital for assessment of neutropenic fever. The patient underwent a flexible bronchoscopy and debridement of necrotic tumor and the right upper, middle and lower lobes were all open at completion of the procedure. Three days after being admitted for fever, the patient was discharged.



Figure 2 – First treatment (pre light activation).



Figure 3 – First treatment (post light activation).



Figure 4 – Follow-up bronchoscope (5 days following initial treatment).

Clinical Outcomes

The patient had resolution of hemoptysis after his second PDT treatment. Other improvements included improved performance status, resolved dyspnea, and minimal cough. He also had palliation of his life-threatening symptoms. PDT accomplished necrosis and debridement of the entire tumor.

Discussion

This case shows treatment with PDT of a patient's persistent symptoms while on chemotherapy. PDT was considered to be a reasonable option because the patient was not resectable. PDT allowed alleviation of the occlusive cancer and life-threatening hemoptysis.

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.

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.