

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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Stage IV lung cancer with persistent cough

Courtesy of Osita I. Onugha, MD, MBA

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Patient History

This is a 76-year-old female Jehovah's Witness with stage IV right lung adenocarcinoma who was found to have an exon 19 mutation and had good response to erlotinib. However, she presented with persistent cough not allowing her to sleep at night as well as dyspnea. A computed tomography (CT) chest scan was performed that demonstrated near complete narrowing of the right lower lobe bronchus with postobstructive pneumonia.

The patient has a past medical history significant for persistent cough, hypertension, and osteoporosis. On bronchoscopy, endobronchial obstruction of the bronchus intermedius and right lower lobe bronchus was seen, with tumor emanating from the superior segment of the right lower lobe and pathology from biopsy revealing adenocarcinoma.

Examination

The patient had stable vital signs and was in no acute distress. Coughing was present. On examination, she had no lymphadenopathy.

Diagnostic Evaluation

A CT scan of the chest showed narrowing of the right lower lobe and bronchus intermedius with a postobstructive pneumonia. The patient also had a mediastinal soft tissue mass and right hilar lymphadenopathy. She underwent a bronchoscopy with debridement of endobronchial mass. A biopsy was performed, and pathology confirmed adenocarcinoma consistent with stage IV lung cancer. After debridement, the patient had short-term resolution of coughing, which allowed her to sleep.

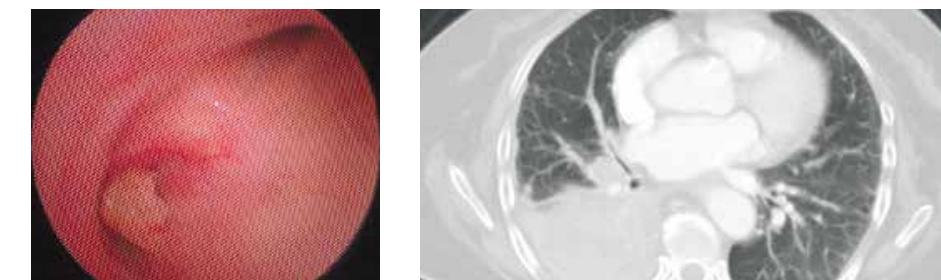


Figure 1 – Bronchoscopy and CT chest pre-PHOTOFRIN® (porfimer sodium) for Injection treatment.

Course of Treatment

Because of the patient's obstructing endobronchial lesion and significant improvement in coughing after initial debridement, she was offered photodynamic therapy (PDT) for more durable control of her persistent cough. She was administered a 2 mg/kg dose of PHOTOFRIN® (porfimer sodium) for Injection intravenously. Forty-eight hours later, the obstructing tumor within the bronchus intermedius was treated using a 2.5-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. Forty-eight hours later, the patient was taken to the operating room for a bronchoscopy, during which the tumor in the bronchus intermedius and right lower lobe bronchus was easily debrided. The bronchus intermedius was 100% patent.

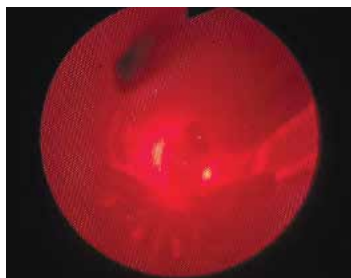


Figure 2 – Bronchoscopy during PHOTOFRIN® treatment.

Clinical Outcomes

After treatment with photodynamic therapy (PDT) to the bronchus intermedius, the patient reported at time of discharge that her cough had completely resolved.

Discussion

This case provides a good demonstration of how PDT can be used as a local treatment modality for advanced lung cancer with endobronchial involvement where radiation or surgery has no role or a very limited role. Local treatment with PDT resulted in macroscopic eradication of endobronchial tumor with significant improvement in cough and dyspnea in a nonsurgical candidate. Proper patient selection is crucial to obtain the best clinical outcome.



Figure 3 – Day 2 initial follow up, after first light, before debridement



Figure 4 – Immediately after debridement

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.

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

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.