

**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.

**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 full Prescribing Information for PHOTOFRIN® (porfimer sodium) for Injection at: [www.photofrin.com](http://www.photofrin.com)**

**FOR MORE INFORMATION** about PHOTOFRIN®, or if there are any questions regarding the information provided, visit [www.photofrin.com](http://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](http://www.fda.gov/medwatch), or call **1-800-FDA-1088**.

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# Successful Ablation Using Photodynamic Therapy for a T2aN0M0 Endobronchial Carcinoid Tumor of the Lung with Curative Intent

**Dr. Abhishek Biswas MD**  
Interventional Pulmonology, Parkview Health, Fort Wayne IN

## Patient History

A 27-year-old otherwise healthy male without any significant past medical history was evaluated for increasing shortness of breath and cough for two weeks. He also reported worsening intensity of chest pain that was aggravated by deep breathing. The patient is a current smoker who has smoked a half pack per day for the past four years.

## Examination

Normal physical examination with reduced breath sounds in the right upper chest.

## Diagnostic Evaluation (or Clinical Impression)

Preoperative CT of the chest revealed an endobronchial nodular density involving the right mainstem and upper lobe bronchi, as well as the bronchus intermedius. The largest dimensions were measured at 1.7 cm in axial dimensions and 1.3 cm craniocaudally ( Figure 1).

The patient underwent bronchoscopy with biopsy of the endobronchial nodule that was noted to partially obstruct the right mainstem bronchus. This was noted to originate from the posterior aspect of the right mainstem and involved the posterior wall of the right upper lobe bronchus (Figure 2).

Figure 1. CT Chest Right Mainstem Obstruction



Figure 2. Right upper lobe nodular lesion



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

Course of Treatment

The tumor was excised with electrocautery snare at the time of the initial biopsy and cryoprobe application was performed several times over the base of the tumor (5-second freeze/thaw). After the snare and cryoprobe application the right mainstem bronchus and upper lobe bronchus were patent. Mediastinal lymph node sampling was then performed systemically and was negative. Endobronchial biopsies collected during the procedure revealed typical carcinoid tumor. 68GA-DOTATE PET showed no evidence of metastasis. The cancer was classified as T2a<sub>central</sub> NOM0, Stage 1b. A repeat bronchoscopy performed one month later revealed scar-like mucosal changes at the site of the excised nodule (Figure 3).



Figure 3. Right secondary carina flat mucosal lesion at site of previous cryoablation.

During the repeat bronchoscopy endobronchial biopsies were obtained and revealed presence of carcinoid tumor. Since there was persistent tumor at the site of the previously excised tumor and the cryotherapy was unable to achieve adequate tumor destruction, the patient met with Cardiothoracic Surgery.

The patient was offered the option of undergoing a right upper lobe lobectomy with plans for right pneumonectomy if the mainstem bronchus could not be spared. The patient preferred to avoid a pneumonectomy and hence we discussed photodynamic therapy to treat the lesion.

Photofrin, PDT Light Applications, and Debridement					
Day 1	Photofrin IV Administration 2 mg/kg				
	Debridement Type	Light Dose <sup>1</sup>	Fiber Length	Fiber Type	Fiber Placement
Day 3	None	200 J/cm	2.5 cm	Flexible	Adjacent, Divided 100 J/cm Posterior & 100 J/cm Anterior Bronchus
Day 5	Forceps	200 J/cm	2.0 cm	Rigid	Adjacent
Day 7	Forceps	N/A	N/A	N/A	N/A

<sup>1</sup> Duration 500 s

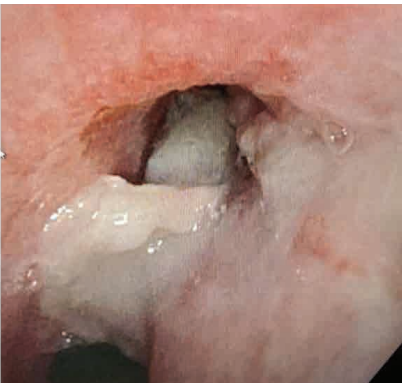


Figure 4. Day 7: Slough after treatment

Clinical Outcomes

A recent bronchoscopy 2 months post PDT; showed scar with no evidence to suggest recurrence of cancer. No endobronchial biopsies were obtained. CT chest did not show any nodule or other abnormality in the previously known area of abnormality (Figure 5).



Figure 1. CT Chest Right Mainstem Obstruction



Figure 5. CT chest showing resolution of the nodule

Discussion

Typical carcinoid of the lung is best treated with lung resection as long as the disease has been proven to be localized to the lung with no evidence of nodal metastasis.

Sometimes, this option may not be practical if a pneumonectomy is essential. Endoluminal therapies have been noted to be of benefit in such situations in achieving cure. PDT has been described to be of use in this clinical scenario. Of all the ablative therapies that we had considered for ablation of typical endobronchial carcinoid, PDT is supported by the most exhaustive body of literature. We offered PDT therapy with the hope to avoid a right pneumonectomy. We will continue to monitor with serial Chest CTs every 6 months and inspection bronchoscopies with biopsies as necessary over the next few years.

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 health care provider, 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.

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.