

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.

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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ADP-012 v.02 08/2020
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PDT With PHOTOFRIN Local Treatment Modality In Recurrent Endobronchial Metastasis

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Phoenix, AZ

Patient History

This 48-year-old male patient was diagnosed with renal cell carcinoma more than 2 years prior admission. He had received treatment with interleukin and temsirolimus, had undergone a right nephrectomy, and his ECOG status was 0-1.

Additionally, the patient had several endobronchial interventions for a recurrent right upper lobe metastatic lesion, including cryoablation, argon plasma coagulation (APC), external beam radiation, and brachytherapy (for tumor ablation and treatment), with recurrence of tumor in the same location. His biopsy from previous bronchoscopies had confirmed renal cell carcinoma metastatic to airways. The patient also presented with hemoptysis, dyspnea, and recurrent post-obstructive pneumonia. He was a nonsmoker and had no exposure history, but comorbidities included hypertension and type 2 diabetes.

The patient had also developed a large necrotizing right upper lobe pneumonia 2 months prior to this presentation that required 6 weeks of intravenous antibiotics.

Examination

Physical examination revealed stable vital signs and no acute distress, although the patient became short of breath with conversation. Upon further examination, he had diminished breath sounds on the right upper lobe. The remainder of the cardiopulmonary exam was unremarkable.

Diagnostic Evaluation

A computed tomography (CT) scan had shown a large endobronchial tumor extending from the right mainstem take off to the right upper lobe, causing complete right upper lobe collapse. A large right hilar mass was also present (Figure 1).

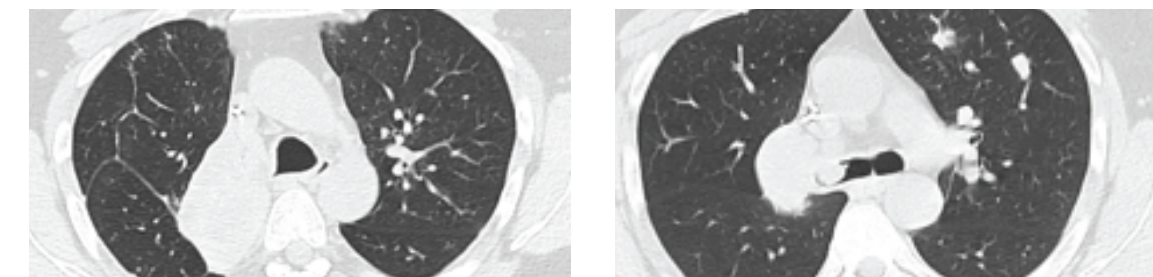


Figure 1 – Chest CT (pre-bronchoscopy and pre-photodynamic therapy [PDT]).

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

Diagnostic Evaluation (Continued)

Bronchoscopy showed vascular tumor close to completely obstructing the right upper lobar bronchus (Figure 2).



Figure 2 – Bronchoscopy image showing right upper lobe lesion (pre-photodynamic therapy [PDT]).

Course of Treatment

Because of the patient's recurrent endobronchial tumor and poor response to other treatments, he was offered photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for Injection as a local modality, along with tumor ablation, to help improve shortness of breath as a palliative modality. The patient received the standard 2 mg/kg of PHOTOFRIN® intravenously. Forty-eight hours later, the obstructing tumor within the right upper lobe of the bronchus was treated using a 2-cm diffusing fiber at an energy setting of 200 Joules/cm for a total of 8 minutes with a wavelength of 630 nm \pm 3 nm (Day 1). Two days later, the same location was re-treated at 200 Joules/cm (Day 3). Between PDT with PHOTOFRIN® procedures, the patient underwent endobronchial debridement of tumor (Day 5).

Clinical Outcomes

Two days after his third bronchoscopy and PDT treatment with PHOTOFRIN® to the right upper lobe of the bronchus, additional oxygen was no longer required. The patient's dyspnea and hemoptysis improved significantly. Additionally, the atelectasis of the right upper lobe showed marked improvement. For over 2 years, the patient had no recurrent pneumonia. The CT image (Figure 3) shows decreased vascularity after first PDT with PHOTOFRIN®.

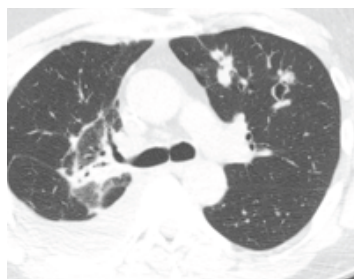


Figure 3 – Chest CT 2 weeks post- PDT with PHOTOFRIN® (porfimer sodium) for Injection.

Bronchoscopy post-photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for Injection showed day 1: right upper lobe completely obstructing vascular lesion (first light application); day 3: decreased vascularity (second light application); day 5: debridement (third light application); and day 7: final bronchoscopy (Figure 4).

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

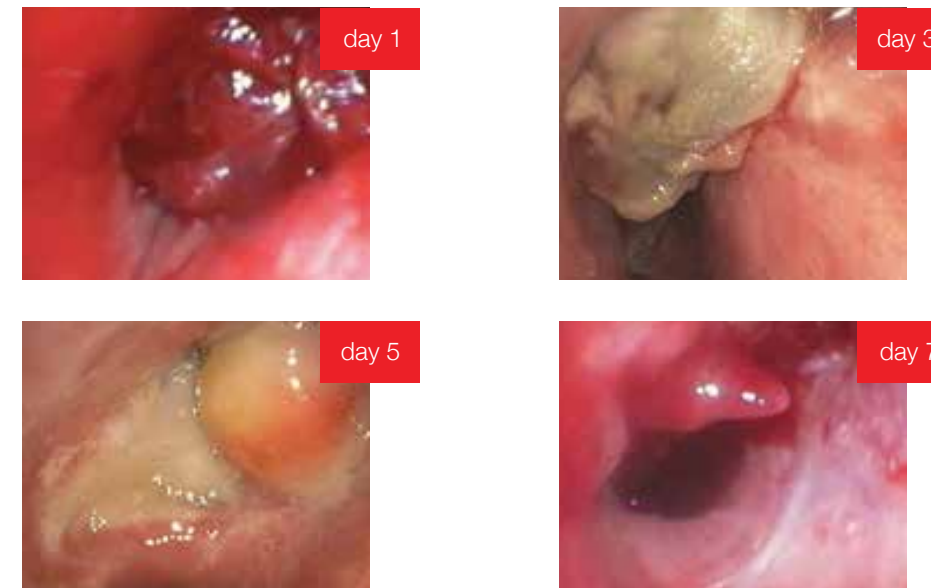


Figure 4 – Bronchoscopy post-photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for Injection, days 1, 3, 5, and 7.

Discussion

This case study shows a clinical scenario in which PDT with PHOTOFRIN® can be used as a local modality for endobronchial lesions in the setting of lobar collapse and recurrent post-obstructive pneumonia. This is especially useful in patients who have extremely vascular lesions, such as renal cell carcinoma with endobronchial obstruction and carcinoid tumors. This can also be useful in patients on high oxygen concentrations where use of endobronchial electrocautery and argon plasma coagulation (APC) may have a risk of explosion or burning. It is important to ensure that there is good lung and open airways distal to the obstruction in these patients. Patient selection is the most important step in efficiently and effectively using PDT with PHOTOFRIN® to achieve optimal patient outcomes.

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.