

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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Treatment of Non-Surgical Esophageal Adenocarcinoma After Failed Endoscopic Submucosal Dissection (ESD)

Courtesy of Kamran Ayub, MD, MRCP, FASGE

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Patient History

This 66-year-old male initially presented with dysphagia (for solids and liquids) and the sensation of a foreign body in his esophagus for the past two months. He has a past history of coronary artery disease s/p Coronary Artery Bypass Graft (CABG), chronic kidney disease, hypertension, diabetes and obesity.

Examination

Physical examination revealed stable vital signs and a BMI of 38.

Diagnostic Evaluation

Endoscopy revealed a nodule in the distal esophagus, and biopsies were positive for adenocarcinoma. Endoscopic Ultrasound (EUS) revealed T1 carcinoma with suspicion of submucosal invasion. Patient was not deemed a candidate for surgery, therefore Endoscopic Submucosal Dissection (ESD) was performed. This revealed T1 carcinoma invading submucosa, extending to the cauterized margins. Patient was presented at the Tumor Board and Photodynamic Therapy (PDT) was recommended.



Endoscopic Images on 11/5/18 prior to first light application

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

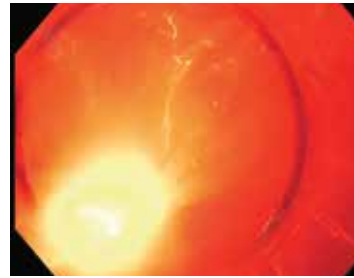
Course of Treatment

The patient received 2mg/kg IV infusion of Photofrin (porfimer sodium) for injection, and an endoscopy with photodynamic therapy was scheduled 3 days after injection.

Day 3 (1st PDT treatment). Due to the level of obstruction it was decided that the light dosimetry was to start with 150 joules.

Fiberoptic Diffuser Selection	
Fiber Type	Rigid Fiberoptic Diffuser
Fiber Length	2.5 cm
Fiber Placement	Endoscopic

Endoscopy & Light Application	
First Light Application	150 J/cm ² × 6min 15 seconds



First Light Application on 11/5/18

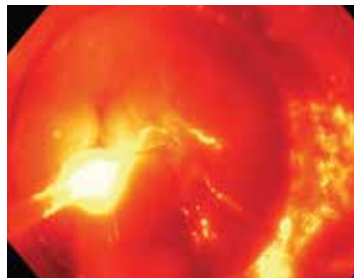


Three Days After First Light Application 11/8/18

Day 6 (2nd PDT treatment). After seeing the initial response the light dosimetry was escalated to 200 joules for the second treatment.

Fiberoptic Diffuser Selection	
Fiber Type	Rigid Fiberoptic Diffuser
Fiber Length	2 cm
Fiber Placement	Endoscopic

Endoscopy & Light Application	
Second Light Application	200 J/cm ² × 8min 20 seconds



Second Light Application on 11/8/18

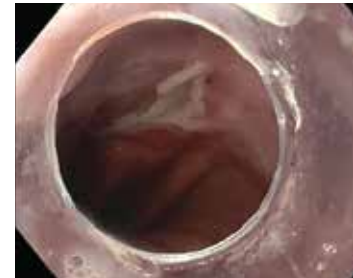
Results of the second light application.



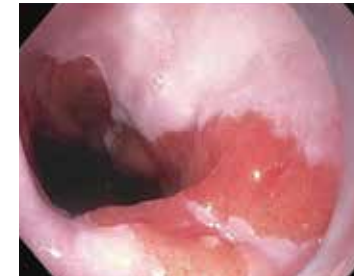
Four Days After the 11/8/18 Light Application (7 Days After First Light Application)

Clinical Outcomes

Repeat endoscopies were done at 1-month, 1-year, and 18-months. During the 1 year endoscopy there was no evidence of malignancy. There was findings of inflammatory atypia almost bordering upon low-grade dysplasia not related to PDT. The most recent 18 month follow up resulted in normal pathology with GERD detected.



1-month Follow-Up



1-year Follow-Up



18-month Follow-Up

Discussion

This case provides a good demonstration of how PDT can be used for patients who failed EMR/ESD treatment and who refuse or do not qualify for esophagectomy.

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.