

CSA Medical Announces New Data at Digestive Disease Week 2019 Supporting the Safety and Efficacy of truFreeze Spray Cryotherapy for Palliation of Esophageal Cancer

– Data show safe and effective palliation prior to chemoradiotherapy for treatment-naïve esophageal cancer patients who presented with dysphagia at diagnosis –

– truFreeze for palliative treatment of esophageal cancer is safe, even in patients with advanced disease –

BOSTON, MA, May 20, 2019 -- CSA Medical today announced the presentation of two clinical abstracts highlighting the safety and efficacy of truFreeze® Spray Cryotherapy for esophageal cancer (EC) palliation. truFreeze uses the extreme cold of liquid nitrogen (-196°C) to provide targeted, touchless ablation of diseased tissue, including cancer, while preserving underlying healthy tissue. The first podium presentation reported positive results from a clinical study evaluating neoadjuvant liquid nitrogen spray cryotherapy administered prior to chemoradiation for EC, and the other, displayed as a poster, reported results from an ongoing study to assess the safety of truFreeze in patients with persistent luminal EC who are not candidates for surgery or who have completed or declined systemic therapy. Both abstracts were presented at Digestive Disease Week® (DDW®) 2019, taking place in San Diego, California, May 18–21.

Study Results

Neoadjuvant Cryotherapy Improves Dysphagia and Increases Remission Rates in Advanced Esophageal Cancer

Presented by Dr. Tilak Shah, MD, Hunter Holmes McGuire VA Medical Center, Virginia Commonwealth University, Richmond, Virginia

Session: Evolving Use of Endoscopy in Esophageal Disease 547; Type: Podium Presentation

This was a prospective, pilot clinical trial to assess the safety and efficacy of liquid nitrogen spray cryotherapy administered prior to chemoradiotherapy in treatment-naïve patients with dysphagia at the time of biopsy-proven squamous cell carcinoma or adenocarcinoma of the esophagus. The primary outcome measure was change in dysphagia at 1 and 2 weeks post-cryotherapy, as measured by the Mellow-Pinkas dysphagia score [0 = no dysphagia; 1 = moderate passage; 2 = poor passage; 3 = very poor passage; and 4 = no passage]; the secondary outcome measure was clinical complete response rate following chemoradiotherapy. A total of 21 patients were enrolled in the study, seven with metastatic EC and 14 with locally advanced disease (one stage 1B, seven stage 2B, three stage 3A, and three stage 3B), each of whom underwent a median of four freeze-thaw cycles during which cryotherapy was applied for 20 to 40 seconds at each cycle. Median tumor length was 5 cm (range: 2 to 12 cm). Key study findings included:

- The primary outcome of dysphagia improvement ≥ 1 point on the Mellow-Pinkas dysphagia score occurred in 15/21 patients (71%) at 1 week and in 10/20 patients (50%) at 2 weeks.
- There were no residual tumor cells identified on mucosal biopsy in 6/9 patients (67%) with locally advanced EC who completed chemoradiation, 5/9 (56%) of whom had a clinical complete response.
- There were no serious cryotherapy-related complications.

The authors concluded that liquid nitrogen spray cryotherapy provides safe and effective palliation for EC patients who present with dysphagia at the time of diagnosis. These results provide the rationale to pursue larger clinical trials to assess the potential synergistic effects of liquid nitrogen spray cryotherapy and chemoradiation.

Liquid Nitrogen Spray Cryotherapy Is Safe for Palliation of Esophageal Cancer: Interim Results from a Prospective Multicenter Study

Presented by Swathi Eluri, MD, MSCR, Assistant Professor of Medicine, Department of Medicine, Division of Gastroenterology and Hepatology at the University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, North Carolina

*Session: Esophagus 2
Sa1274; Type: Poster*

This is an ongoing, prospective trial to evaluate adverse events associated with liquid nitrogen spray cryotherapy in patients with persistent luminal EC who are not surgical candidates, not receiving systemic therapy, and do not have esophageal stent placement or a history of prior spray cryotherapy. The 23 patients currently evaluated have undergone a total of 71 treatment sessions, with an average dose of 90 seconds (3×30 seconds) and a mean follow-up duration of 120.4 days; 39% of the patients have tumor stage 3 or 4, 96% have esophageal adenocarcinoma, and 65% have a history of prior chemoradiation. Key study findings included:

- Procedure-related adverse events occurred in one patient (4.0% of 23 patients and 4.2% of 71 procedures). This patient had two episodes of worsening dysphagia during the treatment period, as well as one (1.4%) episode of chest pain that occurred during follow-up. The patient's chest pain resolved, but dysphagia persisted.
- There were no procedure-related serious adverse events.
- There were four procedure-unrelated deaths, two of which were attributed to progression of EC.

The authors concluded that liquid nitrogen spray cryotherapy is safe for palliative treatment of EC, even in patients with advanced disease, with an overall complication rate of 4.2%. Ongoing assessment of this cohort will delineate the efficacy of this approach.

“Both sets of data add to the evidence supporting the clinical utility of the truFreeze Spray Cryotherapy System for palliation of dysphagia in newly diagnosed EC patients, as well as those with advanced disease,” said Wendelin Maners, CSA Medical’s President. “The inability to eat normal foods has a substantial impact on quality of life for patients and their families, and we hope that the data presented at DDW underscores the benefits of adding spray cryotherapy in both patient populations.”

To learn more about the truFreeze® Spray Cryotherapy System, visit <https://csamedical.com/trufreeze/>.

About CSA Medical and truFreeze®

CSA Medical, Inc. develops and manufactures proprietary, interventional spray cryotherapy technology platforms harnessing the power of liquid nitrogen spray delivered by software driven devices with specialty catheters. Extremely cold (-196°C) liquid nitrogen spray flash freezes and

destroys unwanted tissue while enabling a rejuvenative pattern of healing. CSA manufactures and distributes the truFreeze® system in the USA and is currently being utilized in over 125 leading hospitals and universities advancing therapy for patients affected by conditions such as Barrett's esophagus, esophageal cancer, and benign and malignant airway obstructions. To learn more about CSA Medical's technology, please visit www.csamedical.com. truFreeze is a registered trademark of CSA Medical, Inc.

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18-21, 2019, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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