

CSA Medical Announces Data Presented at Digestive Disease Week 2019 Supporting truFreeze Spray Cryotherapy for the Treatment of Barrett's Esophagus

– Results from a multicenter registry show that 87% of patients treated with liquid nitrogen spray cryotherapy achieved complete eradication of dysplasia and 65% achieved complete eradication of intestinal metaplasia –

– Data from a systematic review and meta-analysis of cryotherapy show that complete eradication was achieved in 81% of patients with dysplasia and 66% of patients with intestinal metaplasia, with adverse events in 5.8% of patients –

– Findings from a multicenter registry show that the durability of successful treatment of intestinal metaplasia with liquid nitrogen spray cryotherapy is comparable to that of other ablation modalities –

BOSTON, MA, May 20, 2019 -- CSA Medical today announced the presentation of three clinical abstracts highlighting truFreeze® Spray Cryotherapy for treatment of Barrett's esophagus (BE). truFreeze uses the extreme cold of liquid nitrogen (-196°C) to provide targeted, touchless ablation of diseased tissue while preserving underlying healthy tissue. The first abstract reports positive results from a prospective study evaluating rates of eradication of dysplasia and intestinal metaplasia following treatment with liquid nitrogen spray cryotherapy in patients who are enrolled in a multicenter national registry. The second abstract highlights the results of a systematic review and meta-analysis of 20 studies in which liquid nitrogen-based, carbon dioxide-based, or nitrous oxide-based cryotherapy was used to treat BE. The third abstract reports results from a study evaluating the rate of recurrence of intestinal metaplasia following its complete eradication with liquid nitrogen spray cryotherapy in patients enrolled in a multicenter national registry. Abstracts were presented at Digestive Disease Week® (DDW®) 2019, taking place in San Diego, California, May 18–21.

"These studies underscore the clinical benefits of spray cryotherapy in early esophageal disease, including BE," said Wendelin Maners, CSA Medical's President. "We are excited to be sharing new data for truFreeze, which is the only cryo ablation technology with years of clinical data for addressing BE to cancer. These findings add to the growing body of data reinforcing the importance of incorporating truFreeze into the treatment regimen for BE patients."

Study Results

Poster of Distinction: Liquid Nitrogen Spray Cryotherapy Eradicates Dysplasia in 87% and Intestinal Metaplasia in 65% of Patients with Barrett's Esophagus: Results of a U.S. Multicenter Registry

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: Barrett's Esophagus: Diagnosis, Management and Surveillance

Sa1137; Type: Poster Presentation

This study evaluated rates of eradication of dysplasia and intestinal metaplasia in a real world setting in patients who were enrolled prospectively in a multicenter national registry and had undergone liquid nitrogen spray cryotherapy. Among the 210 patients, 114 met efficacy analysis criteria for complete eradication of dysplasia and intestinal metaplasia. At baseline, 53% of patients had high-grade dysplasia, 24% had low-grade dysplasia/indefinite dysplasia, 24% had intestinal metaplasia, and 3% had non-dysplastic BE. Patients received a median of three spray cryotherapy sessions. Key findings included:

- 87% (97 patients) achieved complete eradication of dysplasia and 65% (74 patients) achieved complete eradication of intestinal metaplasia, with a median of three spray cryotherapy sessions.
- When patients with intramucosal adenocarcinoma were excluded, 90% achieved complete eradication of dysplasia and 64% achieved complete eradication of intestinal metaplasia.
- Among the 65 treatment-naïve patients, 88% achieved complete eradication of dysplasia and 72% achieved complete eradication of intestinal metaplasia.
- Patients achieved complete eradication of intestinal metaplasia over a median of 10 (range: 1 to 48) months and received on average three (range: 1 to 10) total treatment sessions (ablation or endoscopic mucosal resection) and two (range: 1 to 6) spray cryotherapy sessions.
- The 35% of patients who did not achieve complete eradication of intestinal metaplasia underwent a median of 5 ablation sessions, of which four were spray cryotherapy treatments over 18 (range: 1 to 45) months.
- There were seven procedure-related complications (6.1% of patients and 2.1% of 336 procedures): Five strictures & two episodes of abdominal pain.
- Longer BE segments (4.4 ± 2.8 cm vs. 2.7 ± 2.4 cm; $p = 0.01$) and prior ablation (53% vs. 72%; $p = 0.04$) were associated with incomplete eradication.

Efficacy of Cryotherapy as a Primary Treatment for Dysplastic Barrett's Esophagus and Early Esophageal Neoplasia: A Systematic Review and Meta-Analysis

Presented by Raseen Tariq, MD, Rochester General Hospital, Rochester, New York and Vivek Kaul, MD, Center for Advanced Therapeutic Endoscopy, Gastroenterology and Hepatology, University of Rochester Medical Center, Rochester, New York

Session: Esophagus 1

Mo1172; Type: Poster

This systematic review and meta-analysis included 20 studies, 13 of which used liquid nitrogen-based cryotherapy, 5 of which used carbon dioxide-based cryotherapy, and 2 of which used nitrous oxide-based cryotherapy as primary treatment of BE. Key findings included:

- In the 19 studies reporting complete eradication of dysplasia, 81.0% of patients achieved this outcome.
- In the 15 studies reporting complete eradication of intestinal metaplasia, 66.0% of patients achieved this outcome.
- When the analysis was limited to the 12 published studies (i.e., abstracts excluded), 73.0% of patients achieved complete eradication of dysplasia and 59.0% achieved complete eradication of intestinal metaplasia.
- Adverse events occurred in 5.8% of patients (most commonly post-procedural pain, esophageal strictures, and self-limiting dysphagia).

The authors concluded that cryotherapy is a safe and effective primary therapy for dysplastic BE and early esophageal neoplasia, with rates of complete eradication comparable to those reported in the literature for other ablation modalities. Accordingly, cryotherapy should be considered as primary therapy for dysplastic BE and early neoplasia when discussing ablation modalities with eligible patients.

Durability of Successful Eradication of Barrett's Esophagus with Liquid Nitrogen Spray Cryotherapy: Results of a U.S Multicenter Registry.

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: Barrett's Diagnosis and Therapy
639; Type: Podium*

This study evaluated rates of recurrence of intestinal metaplasia after complete eradication in patients who had undergone liquid nitrogen spray cryotherapy while enrolled prospectively in a multicenter national registry, thereby assessing the durability of this procedure in the setting of BE. Among the 214 patients, 114 were ≥ 365 days beyond initial cryotherapy. Of these 114 patients, 74 (65%) achieved complete eradication of intestinal metaplasia; 56 of these 74 patients had post-eradication surveillance biopsies and were included in the data analysis. Key study findings included:

- The most common pathology at baseline was high-grade dysplasia (50%), followed by intramucosal adenocarcinoma (30%), low-grade dysplasia/indefinite dysplasia (18%), and non-dysplastic BE (2%).
- Mean BE segment length was 2.7 ± 2.4 cm.
- Over an average of 9 months, patients were treated with one to six spray cryotherapy sessions at a median treatment dosimetry of two (range: 1 to 4) cycles with a spray time of 20 (range: 18 to 30) seconds/site.
- Average follow-up time after complete eradication of intestinal metaplasia was 20.4 ± 11.5 months.
- Intestinal metaplasia recurred in 19.6% (11 patients) of those who initially achieved complete eradication; 14.3% of recurrent intestinal metaplasia was non-dysplastic.

The authors concluded that the durability of successful treatment of intestinal metaplasia with liquid nitrogen spray cryotherapy is comparable to that of other ablation modalities.

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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