

STUDIES FURTHER VALIDATE SAFETY, EFFICACY AND AN IMPROVED PATIENT EXPERIENCE IN USE OF THE C2 CRYOBALLOON[®] ABLATION SYSTEM FOR PRIMARY TREATMENT OF BARRETT'S ESOPHAGUS

REDWOOD CITY, Calif. – May 9, 2017 – C2 Therapeutics marked Digestive Disease Week by releasing the results of clinical studies that help further validate the utility of the C2 CryoBalloon[®] Ablation System (CbAS) for ablation of Barrett's esophagus.¹

These include studies that suggest a shorter physician learning curve with CbAS than for radiofrequency ablation (RFA) therapy and less pain two days post-procedure than with RFA. Further studies demonstrate potential for CbAS in ablation of gastric antral vascular ectasia (GAVE) and esophageal squamous cell neoplasia (ESCN).

The CbAS is similar to RFA in being deployed with an endoscopic catheter but uses extreme cold instead of heat to destroy diseased tissue in the esophagus. In a procedure known as cryoballoon ablation, nitrous oxide (N₂O) cryogen is delivered through a handheld controller in combination with a self-sizing balloon catheter that is inserted into the working channel of a 3.7 mm therapeutic endoscope. The CbAS has been used in nearly 900 procedures to date.

The synopses of the study results released for Digestive Disease Week are:

Physician Learning Curve. Studies show that physicians must perform about 30 RFA procedures to overcome the effect of learning curve on treatment outcomes.¹ This study aimed to determine the learning threshold for ablation of Barrett's esophagus with the CbAS. The researchers analyzed prospectively collected cryoablation procedure data from patients with neoplastic Barrett's esophagus treated at a single academic institution. They concluded that the learning curve effect for CbAS is reached at about 18 cases, after which efficiency plateaus.

Patient Experience. Two studies in the Netherlands² compared post-procedural pain in 79 Barrett's esophagus patients treated with RFA patients and 20 treated with focal cryoballoon ablation. In both studies, all visible Barrett's esophagus was treated, including circumferential treatment of the gastroesophageal junction. Pain was assessed immediately after the procedures and by telephone on Day 2. Patients were asked to apply pain scores from zero (no pain) to 10 (worst pain possible). Immediately after the procedure, 53% of cryoballoon ablation patients reported severe pain (score greater than 3), versus 24% of RFA patients. However, on Day 2, 46% of RFA patients reported severe pain, versus 18% of cryoballoon ablation patients. "This could suggest a shortened pain course after cryoballoon ablation compared with RFA," said the principal investigator Prof. Bas Weusten, Gastroenterology & Hepatology, St. Antonius Hospital, Nieuwegein, Netherlands.

¹ George Kunnackal John, et al, Cryoballoon Ablation for Barrett's Esophagus: A Prospective Single Operator Learning Curve and Time-Efficiency Study, TU1170, AB560 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 5S, 2017.

² Sanne N. van Munster, et al, Post-Procedure Pain Associated with Endoscopic Ablation Therapy of Barrett's Esophagus: Post-Hoc Comparison Between Radiofrequency Ablation and Cryoballoon Ablation, TU1186, AB560 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 5S, 2017.

Treatment for ESCN. Esophageal squamous cell cancer arises from esophageal squamous cell neoplasia (ESCN) and is highly lethal. A multi-site study³ assessed the safety and efficacy of focal cryoballoon ablation for eradicating ESCN. Forty-two patients (98%) were successfully treated. Thirty-five of 40 patients (88%) had complete eradication of unstained lesions (USL) upon a single treatment session; five patients (12%) with persistent USL were successfully re-treated. Three developed superficial self-limited mucosal laceration upon balloon inflation; two of these were successfully treated three months later and one did not return. Dr. Gui-Qi Wang, Department of Endoscopy, Cancer Institute and Hospital Chinese Academy of Medical Sciences in Beijing, China stated, “Although longer-term follow-up data is pending, early results of our multicenter study suggest that focal cryoballoon ablation is safe, well-tolerated and highly effective in inducing complete endoscopic and histologic response.”

Treatment for GAVE. GAVE is an uncommon cause of upper gastrointestinal bleeding. Endoscopic management has been mainly thermoablative, but balloon cryoablation is emerging as an alternative. This multi-center study⁴ reviewed data from 10 patients with refractory GAVE who were treated with balloon cryotherapy. These were patients who continued to receive treatment for GAVE despite prior non-cryoballoon therapy. Each patient received one to four cryoballoon treatments (median two). Technical success was achieved in all patients. Follow-up endoscopy showed improvement in eight patients; one patient showed no improvement in the three months post-cryotherapy. No adverse events were reported. “Cryoballoon therapy is a feasible and safe modality that can be used to treat GAVE,” reports Dr. Amrita Sethi, Division of Digestive and Liver Disease, Columbia University Medical Center, New York, NY. “Further studies are needed to evaluate long-term outcomes for this modality and to compare results to standard therapies.”

Swipe Cryoballoon Ablation Technique. Ablation devices for dysplastic Barrett’s esophagus are effective, but none offer the attributes for widespread adoption because of length of procedure time and ease of use. Other factors include side effects and lack of predictability of ablation depth.. This multi-center study⁵ evaluated the safety, feasibility and dose response of a novel swipe balloon catheter developed by C2 Therapeutics (to be marketed as the C2 CryoBalloon® 90 Ablation System), which delivers 3 cm of ablation in less than 60 seconds. The technique was tested in domestic swine and six human patients. The swipe technique delivered uniform and predictable ablation with mucosal and submucosal necrosis in animal and human esophagus. All the animals tolerated the ablations without difficulty and were able to eat and gain weight afterward. The human patients also tolerated the procedure without adverse events. Investigators concluded that because of its ease of use, the device merits further clinical study in treating dysplastic Barrett’s esophagus.

“These studies reinforce C2 Therapeutics’ commitment to improving treatment for patients affected by Barrett’s esophagus and other diseases of the gastrointestinal system,” said Peter Garcia-Meza, President and CEO. “We continue to develop new design configurations to treat unmet needs in patients with diverse anatomy and disease characteristics. We sincerely appreciate the dedication and support of our collaborating study investigators and participating trial centers.”

³ Yan Ke, et al, Safety and Efficacy of Endoscopic Focal Cryoballoon Ablation for the Treatment of Esophageal Squamous Cell Intraepithelial Neoplasia, MO1997, AB560 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 5S, 2017.

⁴ Anish Patel, et al, Endoscopic Management of Refractory Gastric Antral Vascular Ectasia (GAVE) with Cryoballoon Therapy: A Case Series, MO1986, AB560 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 5S, 2017.

⁵ Brian E. Louie, et al, Evaluation of a Novel Swipe Cryoballoon Ablation System in Bench, Porcine, and Human Esophagus, MO2010, AB560 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 5S, 2017.

About Barrett's Esophagus

Barrett's esophagus develops as a result of chronic injury from gastroesophageal reflux disease (GERD). Over time, the normal esophageal lining is replaced with abnormal cells (Barrett's esophagus), putting patients at greater risk of developing cancer of the esophagus.

About C2 Therapeutics

Founded in 2007 and headquartered in Redwood City, California, C2 Therapeutics developed the C2 CryoBalloon[®] Ablation System for use as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's esophagus with dysplasia. Acquired by Pentax Medical – a division of HOYA Group – in January 2017, C2 Therapeutics continues to innovate and enhance its C2 CryoBalloon[®] Ablation System as a new standard for simplicity in the eradication of esophageal disease.

For more information about C2 Therapeutics, please visit www.c2therapeutics.com.

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¹ C2 CryoBalloon Focal Ablation System is intended for use as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's esophagus with dysplasia.