

Tiny Flexible Microscope Rules Out Early Esophageal Cancer During Standard Endoscopy Procedures

Findings Should Lead to More Efficient Biopsy Practices

Data on Cellvizio® Highlighted In Distinguished Oral Presentation at Digestive Disease Week 2009

CHICAGO – June 3, 2009 – Physicians can easily rule out early esophageal cancer by adding Cellvizio, the world's most miniaturized and flexible microscope, to standard upper endoscopy procedures, according to data presented here Tuesday during a Distinguished Oral Presentation (#854) at Digestive Disease Week® (DDW) 2009. A separate pilot study (Abstract W1362) presented at DDW today further confirmed these results and found that different users draw very similar conclusions when interpreting Cellvizio video sequences.

“Cellvizio’s sharp, real-time, microscopic image sequences of the GI tract allow us to avoid taking biopsies of normal esophageal tissue, saving time, costs and reducing risk of biopsy-related complications when monitoring patients with Barrett’s esophagus,” said Alexander Meining, MD, Associate Professor of Medicine, Department of Medicine II, Technical University of Munich. “Cellvizio should lead to a shift away from the current random biopsy practice.”

Barrett’s esophagus is a condition of the esophagus usually resulting from prolonged gastroesophageal reflux disease (GERD) that potentially leads to esophageal cancer, the fastest growing cancer in the U.S. However, standard endoscopic imaging modalities fail to differentiate the pre-cancerous from benign tissue in the Barrett’s segment, so physicians take random biopsies (as many as a few dozen per patient) in hopes that it represents an accurate sample.

In the multi-center study led by Dr. Meining, physicians used Cellvizio to capture video sequences of around 700 randomly-selected areas in the esophagi of 68 patients with Barrett’s esophagus and recorded their interpretation of the images. They then removed tissue at those exact sites and sent it to the lab for analysis. Of the 703 biopsies that were sent out, only 59 or 8.4% were confirmed to be cancerous or pre-cancerous; 644 were deemed normal.

In the on-site analysis, Cellvizio generated specificity or a true negative rate of 95% and a 92% negative predictive value, meaning that there’s a 92% chance that the target tissue deemed normal with Cellvizio was in fact normal. The Cellvizio images were sent to a different physician for a blinded analysis, who generated 90% specificity and 96% negative predictive value when viewing the image sequences.

“Had the physicians used the Cellvizio cellular-level images to guide their biopsy decisions, they would have been able to dramatically decrease the number of tissue samples they removed from these patients,” Meining said. “Given these findings, Cellvizio should be used to enable more efficient biopsy practices, which will ultimately improve patient care and significantly reduce lab costs and time associated with analyzing normal tissue.”

Michael B. Wallace, M.D., Director of Research for the Department of Medicine and the Division of Gastroenterology and Hepatology at Mayo Clinic, Jacksonville, presented data from the separate pilot study conducted at Mayo Jacksonville, Columbia-Presbyterian Hospital in New York, the Veterans Affairs Hospital in Kansas City, Mo., and Dr. Meining’s site in Munich. This study was designed to determine physicians’ ability to diagnose malignancy in the esophagus as well as to rule it out with Cellvizio images – and to measure how well they agreed on Cellvizio image interpretation.

The nine participating physicians were 90.5% accurate overall in diagnosing pre-cancerous esophageal tissue from 40 previously-captured Cellvizio videos sequences. They accurately differentiated the pre-cancerous tissue 88% of the time and accurately deemed benign tissue as truly benign in 94% of the cases (range 75-100%). The physicians most experienced with the Cellvizio system had an overall accuracy of 97% with sensitivity of 94% and specificity of 100%.

The interobserver agreement for all nine experts was very good with an intraclass correlation coefficient (ICC) (equivalent to Kappa) of 0.72 (with a 95% confidence interval of 0.57-0.85, which means that if the study were repeated, there’s less than a 5% chance that the ICC would fall outside the 0.57 to 0.85 range).

“These findings show that the strong agreement between Cellvizio users most likely wasn’t due to chance, underscoring Cellvizio’s potential utility as a more widely-used tool to enhance physicians’ ability to diagnose and rule out disease during standard endoscopy procedures,” Dr. Meining explained.

The four sites, as well as Centre Hospitalier Universitaire in Nantes, France, are expected to enroll up to 110 patients in a study, known as DONT BIOPCE (Detection Of Neoplastic Tissue in Barrett's Esophagus with In vivo Probe-based Confocal Endomicroscopy) to confirm these results (ClinicalTrials.gov Identifier: NCT00795184).

About Barrett’s Esophagus and Esophageal Cancer

Barrett’s Esophagus occurs when gastroesophageal reflux disease (GERD) causes stomach acid to leak back into the esophagus and damage the lining. This can increase the risk of cancer of the esophagus (adenocarcinoma) by 30-50 fold, based on the published literature. Since the 1980s, incidence rates of adenocarcinoma of esophagus (ACE) have been increasing in both genders in developed countries. ACE is the fastest rising malignancy among white men in the United States, with a relative increase even higher than that observed for breast cancer, malignant melanoma, or prostate cancer. From 1975 to 2001, the

incidence of ACE increased sixfold in the United States, from 4 to 23 cases per million (Journal of the National Cancer Institute 2005; 97:142-146).

About DDW®

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, the American Gastroenterological Association (AGA) Institute, and the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 30 – June 4, 2009, at the McCormick Place, Chicago, IL. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org.

About Mauna Kea Technologies

Mauna Kea Technologies, a French company with a multi-disciplinary scientific approach, has developed Cellvizio, a probe-based Confocal Laser Endomicroscopy (pCLE) system that makes dynamic imaging of life at the cellular level a reality. The cellvizio.net scientific knowledge interactive database is enabling an international community of leading scientists and physicians to share their ground-breaking work based on Cellvizio in gastroenterology and various fields of science and medicine. Mauna Kea Technologies is backed by leading life science investors which include The Psilos Group, Seventure and Creadev. For more information about Mauna Kea Technologies, visit www.maunakeatech.com.

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