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Endoscopic visible light spectroscopy: a new minimally invasive technique for the diagnosis of chronic gastrointestinal ischemia.

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Background
The diagnosis of chronic gastrointestinal ischemia (CGI) remains a clinical challenge. Currently, there is no single and simple test with a high sensitivity available for detection of CGI. Visible light spectroscopy (VLS) is a new technique that non-invasively measures mucosal capillary hemoglobin oxygen saturations during endoscopy (T-Stat 303 Microvascular Tissue Oximeter, Spectros Corporation, California). This saturation reflects the adequacy of mucosal perfusion and is therefore lowered in CGI. A recent pilot study using VLS in a few CGI patients showed very promising results in detection of mucosal hypoxemia. In this study we evaluated the actual diagnostic value of VLS for detection of ischemia in a large cohort of patients clinically suspected for CGI.

Methods
Two groups of consecutive patients referred for evaluation of possible CGI were included in this study. Patients underwent endoscopy-guided VLS next to the standard work-up consisting of a combination of gastrointestinal tonometry (TM) and CT or MR abdominal angiography. In the first group of 80 patients, VLS measurements were performed at 5 standard locations (distal oesophagus, corpus, antrum, bulbus and duodenum) during upper endoscopy. Based on these data, thresholds were set for each location for discriminating ischemic regions from non-ischemic regions. In a second cohort of 41 patients, these thresholds were used to diagnose CGI, and the diagnosis compared to the gold standard work-up of TM and radiologic testing. VLS was performed before start of TM and before radiologic diagnostics. All diagnostics results, except for VLS, were discussed in a multidisciplinary team blinded to the VLS results, and a consensus diagnosis (CGI or no CGI) was made.

Results
In the first group of 80 patients significantly lower saturations were measured at the antrum, duodenal bulb, and the descending duodenum in patients diagnosed with CGI vs. those that were not. In addition, the mean saturation (at multiple locations) was significantly lower in CGI patients, as compared to the non-CGI patients. Thresholds for ischemia were determined to be 63% for the antrum, 62% for the duodenal bulb, and 58% for the descending duodenum. Using these thresholds, patients in the second group of 41 patients were tested for CGI. 32 (78%) of the patients in this group were classified pathological indicating ischemia, and 9 (22%) had normal measurements. This compares to 31 (76%) patients that were diagnosed with CGI by TM and radiographic findings and 10 (24%) who were classified as normal by those methods. The sensitivity and specificity of the T-Stat was 90% and 60% respectively.

Conclusions
VLS measurement of mucosal oxygenation during gastroduodenoscopy is a very promising technique for detection of actual mucosal hypoxemia (i.e. ischemia) in patients suspected for CGI. The technique is easy to perform, and shows excellent correlation with TM.

	Antrum	Bulbus	Duodenum	Overall
Ischemia	63.0 ± 5.4*	58.9 ± 5.2*	54.4 ± 6.7*	59.6 ± 3.4*
No ischemia	65.6 ± 3.8*	62.6 ± 4.4*	59.2 ± 4.1*	62.8 ± 2.3*
Threshold	63%	62%	58%	

Table: VLS mucosal saturation in different locations during gastroduodenoscopy (mean ± SD, in percentages)
SD = standard deviation

Spectros markets advanced molecular sensing and imaging devices that shed light on ischemia and cancer. The company's lead product, the T-Stat Tissue Oximeter, was the first medical device FDA-approved as sensitive to ischemia, an insufficient blood flow to tissue. T-Stat is the only commercially-available tissue oximeter that utilizes state-of-the-art visible light spectroscopy (VLS) technology. In clinical use, T-Stat is a real-time, absolute, non-invasive, and continuous tissue monitor that analyzes 260 wavelengths of light, far more than the 2-4 wavelengths used in other monitors for superior accuracy.