Probe-based confocal laser endomicroscopy (pCLE) allows real-time detection of neoplastic Barrett’s esophagus (BE) tissue. However, the accuracy of pCLE in real time has not yet been extensively evaluated. To compare the sensitivity and specificity of pCLE in addition to high-definition white-light endoscopy (HD-WLE) with HD-WLE alone for the detection of high-grade dysplasia (HGD) and early carcinoma (EC) in BE.

International, prospective, multicenter, randomized, controlled trial. Five tertiary referral centers. A total of 101 consecutive BE patients presenting for surveillance or endoscopic treatment of HGD/EC. All patients were examined by HD-WLE, narrow-band imaging (NBI), and pCLE, and the findings were recorded before biopsy samples were obtained. The order of HD-WLE and NBI was randomized and performed by 2 independent, blinded endoscopists. All suspicious lesions on HD-WLE or NBI and 4-quadrant random locations were documented. These locations were examined by pCLE, and a presumptive diagnosis of benign or neoplastic (HGD/EC) tissue was made in real time. Finally, biopsies were taken from all locations and were reviewed by a central pathologist,
blinded to endoscopic and pCLE data. Diagnostic characteristics of pCLE. The sensitivity and specificity for HD-WLE were 34.2% and 92.7%, respectively, compared with 68.3% and 87.8%, respectively, for HD-WLE or pCLE (P = .002 and P < .001, respectively). The sensitivity and specificity for HD-WLE or NBI were 45.0% and 88.2%, respectively, compared with 75.8% and 84.2%, respectively, for HD-WLE, NBI, or pCLE (P = .01 and P = .02, respectively). Use of pCLE in conjunction with HD-WLE and NBI enabled the identification of 2 and 1 additional HGD/EC patients compared with HD-WLE and HD-WLE or NBI, respectively, resulting in detection of all HGD/EC patients, although not statistically significant. Academic centers with enriched population. pCLE combined with HD-WLE significantly improved the ability to detect neoplasia in BE patients compared with HD-WLE. This may allow better informed decisions to be made for the management and subsequent treatment of BE patients. (Clinical trial registration number: NCT00795184.)