Direct visualization of indeterminate pancreaticobiliary strictures with probe-based confocal laser endomicroscopy: a multicenter experience.

Because of the low sensitivity of current ERCP-guided tissue sampling methods, management of patients with indeterminate pancreaticobiliary strictures is a challenge. Probe-based confocal laser endomicroscopy (pCLE) enables real-time microscopic visualization of strictures during an ongoing ERCP. To document the utility, performance, and accuracy of real-time pCLE diagnosis compared with histopathology, a prospective observational study within the framework of a multicenter registry. Five academic centers. This study involved 102 patients with indeterminate pancreaticobiliary strictures. Clinical information, ERCP findings, tissue sampling results, and pCLE videos were collected prospectively. Investigators were asked to provide a presumptive diagnosis based on pCLE during the procedure before pathology results were available. All patients received at least 30 days of follow-up until definitive diagnosis of malignancy was established or 1-year follow-up if index tissue sampling was benign. Diagnostic accuracy, sensitivity, specificity of ERCP-guided pCLE compared with ERCP with tissue acquisition. There were no pCLE-related adverse events in the study. We were able to evaluate 89 patients, of whom 40 were proven to have cancer. The sensitivity, specificity, positive-predictive value,
and negative-predictive value of pCLE for detecting cancerous strictures were 98%, 67%, 71%, and 97%, respectively, compared with 45%, 100%, 100%, and 69% for index pathology. This resulted in an overall accuracy of 81% for pCLE compared with 75% for index pathology. Accuracy for combination of ERCP and pCLE was significantly higher compared with ERCP with tissue acquisition (90% vs 73%; P = .001). Investigators had access to all relevant clinical information, which may have biased the predictive characteristics of pCLE. Probe-based CLE provides reliable microscopic examination and has excellent sensitivity and negative predictive value. The significantly higher accuracy of ERCP and pCLE compared with ERCP with tissue acquisition may support supplementing ERCP with pCLE.