VLESPOTLIGHT

NvisionVLE* | Imaging System

CASE STUDY: VLE for Pre-Treatment Planning using Real-time Targeting[™]

PATIENT HISTORY

A 58 year old male presented with a history of gastroesophageal reflux disease (GERD) and long segment Barrett's Esophagus (BE). During a prior exam, pathology returned high grade dysplasia (HGD) and suspected intramucosal carcinoma (IMCA). The purpose of this procedure was to localize areas of HGD and suspected IMCA using the NvisionVLE® Imaging System and then use Real-time Targeting™ (RTT) to mark areas for treatment.

PROCEDURE

ENDOSCOPIC EXAM

The esophagogastroduodenoscopy (EGD) showed a very long segment of BE extending circumferentially from 35cm-20cm (Prague Criteria C15 M15). No mucosal abnormalities were observed under white light endoscopy (WLE) or narrow band imaging (NBI).

VLE -

Volumetric Laser Endomicroscopy

The extent of the BE region was imaged in real-time using the NvisionVLE® Imaging System. At the proximal range of the BE, a region of suspicion was identified between 26-23 cm. Using RTT, tissue laser marking was performed surrounding the region of interest in order to guide treatment with endoscopic mucosal resection (EMR).



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Figure 1: White light endoscopy (top) and narrow band imaging (bottom) of the proximal region of BE

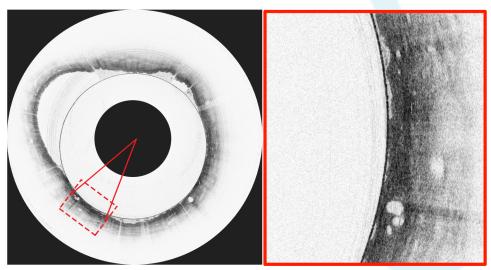


Figure 2: NvisionVLE® Imaging System data in the proximal region of BE. Full transverse scan (left) and accompanying zoomed image region (right) showing one particular area of concern.

Twelve tissue laser marks were made surrounding the suspicious region using RTT, in addition to a center mark to confirm EMR location. Five EMR's were taken from the margins determined using the NvisionVLE® RTT system.

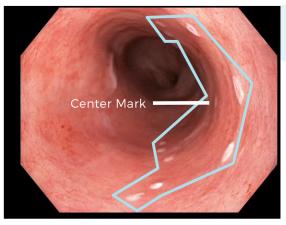


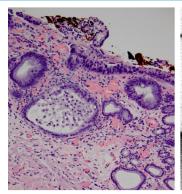


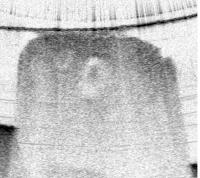
Figure 3: Thirteen Real-time Targeting™ tissue laser marks visible under white light endoscopy, used to guide five EMRs (left). EMR region after tissue removal (right).

RESULTS

Mucosal tissues removed via EMR were scanned *ex vivo* using VLE to verify that regions of suspicion were captured. Pathology confirmed HGD with focus suspicious for IMCA.

Figure 4: Pathology image from EMR specimen (left). Pathology confirmed HGD with focal suspicion for IMCA in the VLE-guided tissue region of suspicion. *Ex vivo* VLE scan of the matching EMR specimen (right).





DISCUSSION -

The intent of this procedure was to localize areas of HGD and suspected IMCA within a 15 cm segment of BE which showed no signs of mucosal abnormality under WLE or NBI. Using the new NvisionVLE® Imaging System with Real-time Targeting™, it was possible to navigate through the esophagus to determine abnormal mucosa, apply superficial tissue laser marks, and define margins for resection, all in real-time. The areas of most concern were found in the proximal portion of the BE segment. The mucosal abnormalities that included atypical glands containing visible debris were sampled and confirmed by two pathologists as HGD with dilated glands suspicious for IMCA. Although continued studies will be required to prove the broader impact of Advanced OCT and laser marking in the management of Barrett's related dysplasia, its impact on this particular patient is undeniable.



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The NvisionVLE® Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue. The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.