VLESPOTLIGHT

NvisionVLE* Imaging System

CASE STUDY: VLE for Post-Treatment Assessment

PATIENT HISTORY

This patient was originally referred with nodular esophageal disease that was endoscopically visible at the Gastro-Esophageal Junction (GEJ). The area was treated using combination Cryotherapy and Endoscopic Mucosal Resection (EMR). (Figures 1-3)



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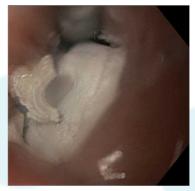


Figure 1: Cryotherapy of Nodule



Figure 2 : Nodule Post Cryotherapy

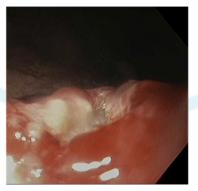


Figure 3: EMR Post Cryotherapy

Pathology of the EMR sample was positive for Adenocarcinoma (Figure 4)

A subsequent surveillance EGD showed the previous EMR site, a normal GEJ, and normal distal esophageal lining. Random biopsies were taken of the treated area and were negative for dysplasia.

This procedure was a second follow-up surveillance exam with the intent to use Advanced OCT to potentially aid in the targeting and localization of any abnormal areas.

Figure 4: EMR pathology: Adenocarcinoma

PROCEDURE

ENDOSCOPIC EXAM

White light endoscopy (WLE) and Narrow Band Imaging (NBI) findings showed the previous EMR area (Figure 5) and otherwise, a normal GEJ and normal distal esophagus.

VLE PROCEDURE

Volumentric Laser Endomicroscopy

Using the NvisionVLE Imaging System, the VLE scan identified a region of glandular atypia at the GEJ, yet approximately 1cm away from the previously treated region (Figure 6). As a result, VLE-targeted biopsies were taken of this newly suspicious area.



Figure 5 : Endoscopic view of previous EMR site

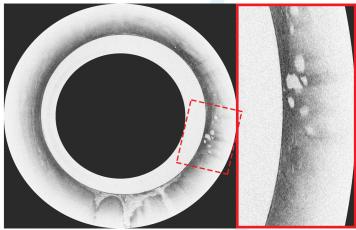


Figure 6: VLE image of deep and focal glandular atypia not seen under WLE or NBI

RESULTS

Although prior random biopsies came back negative for Dysplasia, the VLE-targeted biopsies came back positive for Low Grade Dysplasia - background of Intestinal Metaplasia (Barrett's Esophagus) (Figure 7).

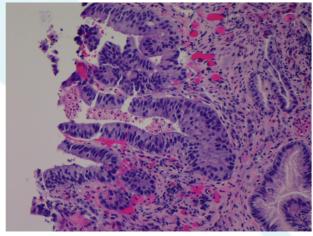


Figure 7 : Pathology of VLE-targeted sample, positive for Low Grade Dysplasia

DISCUSSION •

This case shows the potential for Advanced OCT to identify post-treatment residual disease not seen using high-definition WLE and NBI, and not found using random biopsies. The unique volumetric, high-resolution, perspective provided by the NvisionVLE Imaging System was of particular clinical impact here due to its ability to identify subsurface disease, which subsequently altered the course of treatment for this patient.



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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. 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.