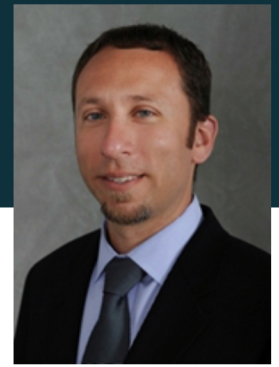


VLESPOTLIGHT

NvisionVLE® | Imaging System



CASE STUDY: VLE for Pre-Treatment Planning

PATIENT HISTORY

A 61 year old male was referred to Dr. Rogart for evaluation/treatment of long segment Barrett's Esophagus (BE) with nodularity. Random biopsies from the referring physician revealed low-grade dysplasia (LGD) and high-grade dysplasia (HGD).

Dr. Rogart first scoped this patient and performed endoscopic mucosal resections (EMR) of nodular areas. Pathology revealed HGD with focal features worrisome of intramucosal carcinoma (IMC).

The intent for this procedure a few weeks later was to assess and evaluate the Barrett's segment using the NvisionVLE Imaging System and possibly perform additional EMRs to achieve clean margins.

PROCEDURE

ENDOSCOPIC EXAM

The esophagus and gastroesophageal junction (GEJ) were examined with white light and narrow band imaging (NBI). BE without nodularity was present from the GEJ (36cm) to the irregular Z-line (27cm). Previous EMR sites were visible under white light (Figure 1), however, no other suspicious areas were evident.

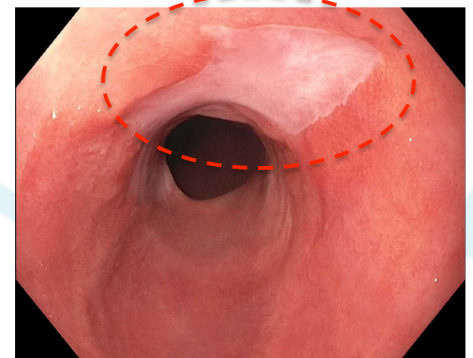


Figure 1: Endoscopic view of previous EMR site.

VLE

Volumentric Laser Endomicroscopy

Cautery marks were placed at 36cm (GEJ), 32cm and 28cm in order to aid in the registration of the VLE image. The NvisionVLE Imaging System was used to capture 9cm of the esophagus starting approximately 1cm below the GEJ; from 37cm to 27cm.

VLE Images were reviewed in real time and showed suspicious appearing glands that were not apparent during the EGD.

- 35cm at 3:30 - Septated atypical glands (Figure 2A)
- 34.4cm at 4:00 - Septated atypical glands (Figure 3)
- 34.3cm at 2:00 - Septated necrotic glands (Figure 4A)
- 33.1cm at 5:30 - Necrotic atypical gland
- 32.8cm at 2:00 - Necrotic atypical glands
- 30.2cm at 2:30 -Atypical glands (Figure 5A)

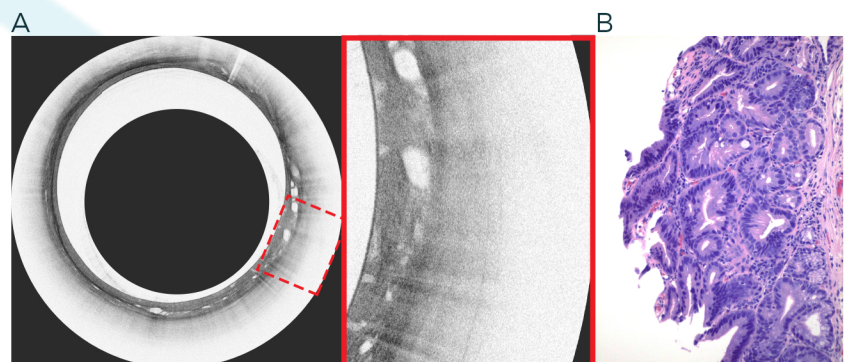


Figure 2:
A. VLE image of a cluster of septated atypical glands, irregular surface and lack of layered architecture.
B. Corresponding pathology (20x) was positive for HGD.

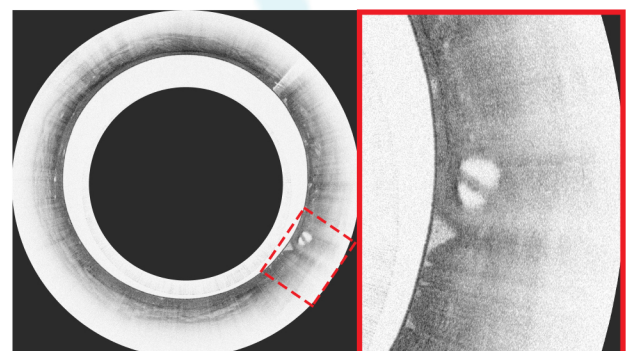


Figure 3: VLE image of septated atypical glands and loss of layered architecture. The pathology was positive for adenocarcinoma.

EMR was performed at 30.2cm utilizing a band ligator and snare. This targeted area was identified solely by VLE (Figure 5A). The other suspicious areas would not lift and suction into the cap and therefore could not be resected. Targeted biopsies were taken at the remaining five suspicious sites.

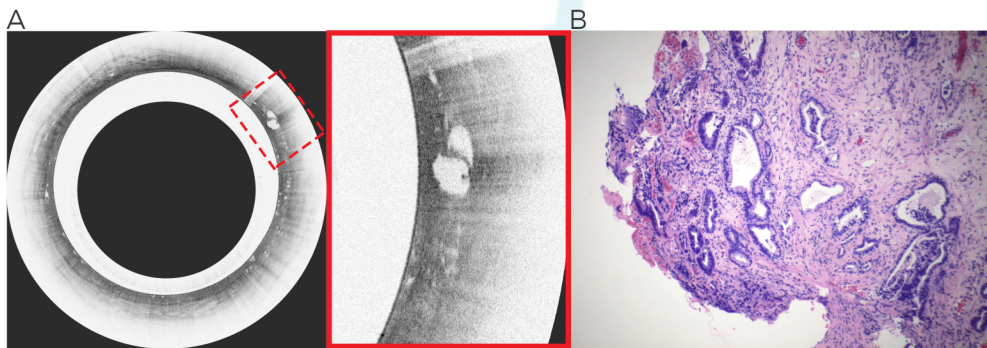


Figure 4:
A. VLE image of septated necrotic glands and effacement of layered architecture.
B. Corresponding pathology (10x) was positive for adenocarcinoma.

RESULTS

The pathology for the EMR specimen that was targeted solely by VLE was positive for HGD (Figure 5B). Biopsies taken from the other VLE-targeted areas came back positive for focal HGD and adenocarcinoma. Surgery consult was recommended.

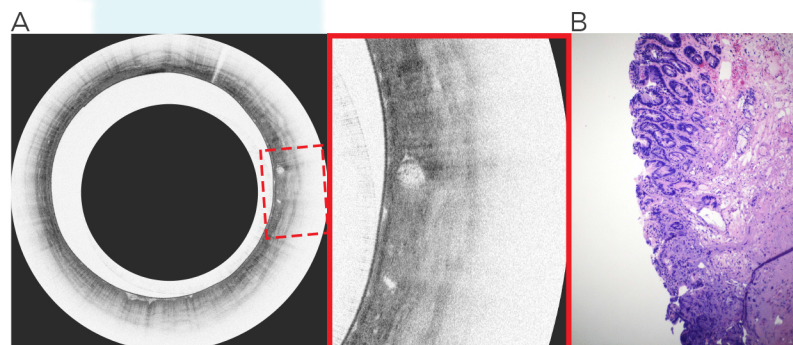


Figure 5:
A. VLE image of atypical glands and irregular surface. An EMR was taken at this site.
B. Corresponding pathology of EMR sample (10x) was positive for HGD

DISCUSSION

This case highlights the benefits of using the NvisionVLE Imaging System for pre-treatment planning. The high resolution VLE images uncovered multiple sub-mucosal areas of abnormality outside of the previous EMR regions that were not visible under white light or NBI. The EMR segment that was positive for HGD as well as the biopsies that were confirmed for focal HGD and adenocarcinoma were all targeted by VLE. These specific findings illustrate the impact that this unique technology had on identifying deep disease, that after multiple endoscopies, biopsies, and treatment, may not have otherwise been found.



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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.