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Title: Evaluation of a novel disposable upper endoscope for unsedated bedside (non-endoscopy unit based) assessment of the upper gastrointestinal (UGI) tract.

Background: Upper endoscopy (EGD) is traditionally performed in an endoscopy unit, emergency department (ED), or ICU. There are several EGD indications where quick non-cumbersome bedside evaluation in a non-traditional setting may be advantageous (i.e. rapid assessment of suspected UGI bleeding—inpatient ward or ED triage; GERD nonresponsive to therapy; dysphagia; clinic based esophageal varices screening). Our academic lab has developed a novel mechanical disposable upper endoscope for unsedated bedside assessment of the UGI tract that can be used off-the-shelf without need for large equipment (i.e. endoscopy cart, monitor, computer) or complex electronics. Performance of the platform in-vivo is unknown.

Methods:

Platform: The disposable novel upper endoscope consists of a 720x480 p camera with LED module attached to the distal end of 3 bellows. A nitinol wire handle compresses air within a series of syringes to actuate the bellows. Compressed air flows along the insertion tube (OD: 14 mm) to the bellows producing camera/LED module articulation. Ports for insufflation and lens cleaning are present. Video can be displayed on any monitor—i.e. tablet, smart phone. Total inclusive material cost is <\$70 USD.

Study: Two-phase assessment of the platform was performed: (1) UGI tract phantom was utilized with gastric landmarks marked (GE junction, body greater & lesser curvature (GC & LC), antrum GC & LC, and incisura). EGD was completed with a traditional gastroscope followed by utilization of the novel endoscope. End-points included successful identification of landmarks and time to identification. (2) UGI tract assessment was performed in a 40 Kg Yorkshire-Landrace swine in-vivo using a traditional gastroscope and the novel endoscope by an experienced endoscopist. End-points included successful identification of landmarks (as above), time to identification, and safety—including leak testing and necropsy.

Results: All 6 landmarks were successfully identified in the phantom and swine using both the traditional gastroscope and novel endoscope. Mean time to landmark identification was shorter for traditional endoscopy when compared to the novel endoscope in both phantom and in-vivo trials (70 v 111 s; 180 v 208 s; $p < 0.01$). There were no adverse events, evidence of endoscopic or gross trauma, perforation, or histologic abnormality at necropsy.

Conclusions: The novel upper endoscope was safe, easy to maneuver, and successful at visualizing key landmarks in the stomach. There were no adverse events or tissue damage in-vivo. Despite longer mean times with the novel endoscope, the times remain within a clinically acceptable range. Our system has the potential to allow for rapid diagnostic unsedated assessment of the UGI tract in non-endoscopy unit or non-ICU based settings to facilitate patient management decisions and minimize equipment encumbrance.

Figure:

