Ultrathin disposable gastroscope for screening and surveillance of gastroesophageal varices in patients with liver cirrhosis: a prospective comparative study

Dep K. Huynh, MBBS, FRACP,[1,2] Leanne Toscano, B Nursing,[1] Vinh-An Phan, MBBS, FRACP,[1,2] Tsai-Wing Ow, MBBS,[1] Mark Schoeman, MBBS, FRACP, PhD,[1] Nam Q. Nguyen, MBBS, FRACP, PhD[1,2]

Adelaide, Australia

Background and Aims: This study aims to evaluate the role of unsedated, ultrathin disposable gastroscopy (TDG) against conventional gastroscopy (CG) in the screening and surveillance of gastroesophageal varices (GEVs) in patients with liver cirrhosis.

Method: Forty-eight patients (56.4 ± 1.3 years; 38 male, 10 female) with liver cirrhosis referred for screening (n = 12) or surveillance (n = 36) of GEVs were prospectively enrolled. Unsedated gastroscopy was initially performed with TDG, followed by CG with conscious sedation. The 2 gastroscopies were performed by different endoscopists blinded to the results of the previous examination. Video recordings of both gastroscopies were validated by an independent investigator in a random, blinded fashion. Endpoints were accuracy and interobserver agreement of detecting GEVs, safety, and potential cost saving.

Results: CG identified GEVs in 26 (54%) patients, 10 of whom (21%) had high-risk esophageal varices (HREV). Compared with CG, TDG had an accuracy of 92% for the detection of all GEVs, which increased to 100% for high-risk GEVs. The interobserver agreement for detecting all GEVs on TDG was 88% ($\kappa = 0.74$). This increased to 94% ($\kappa = 0.82$) for high-risk GEVs. There were no serious adverse events.

Conclusions: Unsedated TDG is safe and has high diagnostic accuracy and interobserver reliability for the detection of GEVs. The use of clinic-based TDG would allow immediate determination of a follow-up plan, making it attractive for variceal screening and surveillance programs. (Clinical trial (ANZCTR) registration number: ACTRN12616001103459.) (Gastrointest Endosc 2017;85:1212-7.)

Abbreviations: CE, capsule endoscopy; CG, conventional gastroscopy; CREV, clinically relevant esophageal varices; GEV1, gastroesophageal varices type 1; GEV2, gastroesophageal varices type 2; GEVs, gastroesophageal varices; LSM, liver stiffness measurement; NPV, negative predictive value; NSBB, non-selective β-blockers; PPV, positive predictive value; STAI, State-Trait Anxiety Inventory; TDG, ultrathin disposable gastroscopy; UGI, upper gastrointestinal; VAS, visual analog scale.

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Current affiliations: Department of Gastroenterology and Hepatology, Royal Adelaide Hospital, Adelaide, South Australia, Australia (1), Discipline of Medicine, University of Adelaide, Adelaide, South Australia, Australia (2).

Reprint requests: Dr Dep Huynh, Department of Gastroenterology and Hepatology, Royal Adelaide Hospital, North Terrace, Adelaide, South Australia 5000, Australia.

INTRODUCTION

Portal hypertension is a common consequence of liver cirrhosis. Approximately 40% to 60% of patients with cirrhosis have gastroesophageal varices (GEVs).[1-3] Bleeding from varices occurs at a rate of 5% to 15% per year, dependent on the size of the varices, presence of decompensated cirrhosis, and high-risk endoscopic features.[4,5] The mortality rate after an episode of variceal hemorrhage is approximately 15% to 25% at 6 weeks.[6-8] Given the high prevalence of varices and mortality related to bleeding, it is recommended that all patients with cirrhosis be screened for varices at the initial diagnosis. Primary prophylaxis should be initiated in the presence of high-risk varices defined as large varices measuring greater than 5 mm and/or the presence of red color signs/red wale signs.[9-12] De novo GEVs develop in patients with cirrhosis at a rate of 5% to 12% per year,[5,13,14] and small varices progress to large varices at a rate of 12% per year.[5] Therefore, all patients not on

non-selective β-blockers (NSBBs) for primary prophylaxis should continue surveillance at 1- to 3-year intervals guided by the presence of varices and/or hepatic decompensation.[15]

Conventional gastroscopy (CG) remains the criterion standard for the diagnosis of GEVs. Current guidelines for endoscopic variceal screening and surveillance come with a considerable health care burden, an increase in the cost of medical care,[16,17] and is an invasive procedure for the patient that requires conscious sedation. Although several non-invasive techniques to predict the presence of GEVs have been evaluated, including biochemical, US parameters, transient elastography, and multidetector computerized tomography of the liver, they either have insufficient accuracy or require further validation, and thus, cannot replace CG as the criterion standard for variceal screening.[1,18-21] Capsule endoscopy (CE) is a semi-invasive technique with modest accuracy for the diagnosis of GEVs, but is less sensitive for small varices and less accurate in the screening population.[22-25]

The thin disposable gastroscope (TDG; E.G. Scan II, IntroMedic, Seoul, South Korea) is a minimally invasive approach to viewing the esophagus. The scope is 3.6 mm in diameter, 100 cm long, and flexible, with a 160° bending angle and 125° viewing angle (Fig. 1). There is an air channel for insufflation but no accessory channel for suction or endoscopic intervention. The ultrathin caliber allows the procedure to be performed with local anesthesia and avoids the need for sedation and the associated adverse events of sedation in cirrhotic patients.[26-29] The recorded images are processed through a laptop computer, which has the potential to allow physicians to perform upper gastrointestinal (UGI) endoscopy for variceal screening in the consultation room, improving accessibility, and eliminating the direct and indirect costs of sedated CG including pre- and post-procedural monitoring, time off work, and additional travel. Therefore, the aim of this study was to assess the feasibility, safety, and accuracy of the TDG in the detection of gastroesophageal varices against CG in patients with liver cirrhosis undergoing screening or surveillance of gastroesophageal varices.

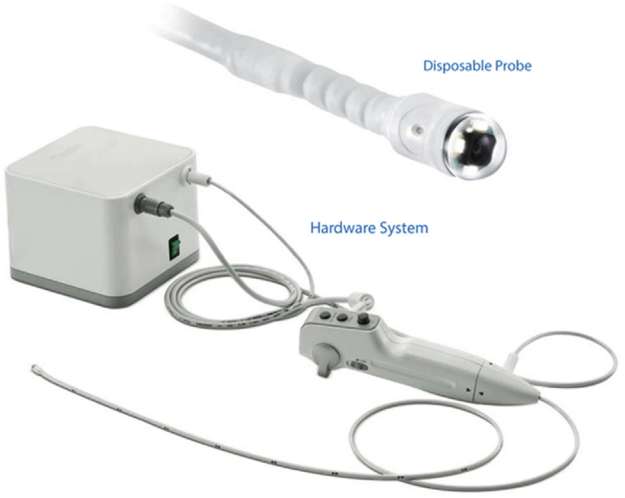

Figure 1. Components of the thin disposable gastroscope.

METHODS

Study population

This was a prospective study of consecutive patients with liver cirrhosis scheduled to undergo UGI endoscopy for variceal screening or surveillance in the Gastrointestinal Investigation Unit of the Royal Adelaide Hospital. Variceal screening was defined as patients with newly diagnosed cirrhosis without previous endoscopic evaluation for the presence of varices. Primary variceal surveillance was defined as patients without previous variceal bleeding, and secondary variceal surveillance was defined as patients with previous variceal bleeding. The inclusion criteria were male or female patients aged 18 to 90 years at the time of consent with clinically or biopsy-proven cirrhosis of any cause. Cirrhosis was defined clinically as chronic liver disease with the presence of portal hypertension (eg, ascites, gastroesophageal varices) or adverse events of cirrhosis (eg, hepatic encephalopathy). Patients were excluded from the study if they were pregnant and/or breastfeeding, if there was evidence of active gastrointestinal bleeding, a history of recent variceal bleed within 7 days, or inability to give written informed consent. The study was reviewed and approved by the Royal Adelaide Hospital Research Ethics Committee (RAH protocol number 130230).

Study procedure

After a 6-hour fast, examination of the upper GI tract with TDG was performed with the patient in the left lateral decubitus position, under laryngeal/pharyngeal local anesthesia, using lignocaine gargle or spray. The transoral route was chosen because of the greater intubation success rate and lower risk of epistaxis previously reported.[30] This was followed by conscious sedation and examination with the CG (Olympus QF 180, Tokyo, Japan) performed by a second gastroenterologist blinded to the preceding TDG result. Digital video recording was captured for both examinations. All TDGs and CGs were performed by the same team of experienced gastroenterologists. All video recordings were de-identified and assessed in random order by an independent investigator blinded to the patient's medical history and the findings of both TDG and CG by the endoscopists.

An assessment was made for the presence or absence of varices, the size of varices classified as small (≤5 mm) or large (>5 mm),[9,10] and the presence of red color signs/red wale signs. Gastroesophageal varices were classified as type 1 (GEV1) if they extended below the gastroesophageal junction along the lesser curvature and type