A novel disposable, transnasal esophagoscope: a pilot trial of feasibility, safety, and tolerance

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A novel disposable transnasal esophagoscope, the E.G. Scan (IntroMedic Co. Ltd., Seoul, Korea), was developed for the evaluation of esophageal diseases while eliminating the inconvenience associated with sterilization, portability, patient monitoring, complications, and the economic burden of sedation. The feasibility, safety, and tolerability of the first version of the E.G. Scan was evaluated in this pilot study. Nasal esophagoscopy was performed successfully in 46 patients with known or suspected esophageal diseases. At least 50 % of the Z-line was visualized by the E.G. Scan in 38 (82.6 %) of 46 patients. Abnormalities were identified in 27 patients: erosive esophagitis (n = 18), Barrett's esophagus (n = 1), esophageal varices (n = 7), and esophageal candidiasis (n = 1). Nasal pain was absent or mild in most patients, and adverse events were not observed. Further technical improvement of the E.G. Scan would increase the diagnostic usefulness in future clinical practice.

Introduction

Surveillance of the esophagus is increasing because it is important to detect benign or malignant esophageal diseases at an early stage. Gastroesophageal reflux disease (GERD), which has been identified in 10 % – 20 % of the population of Western countries [1], significantly impairs quality of life and work productivity [2]. The symptoms can mimic angina pectoris [3] and lead to unnecessary cardiac catheterization [4]. Barrett's esophagus, requires annual endoscopic surveillance to identify dysplasia and its progression to adenocarcinoma [5]. Esophagogastroduodenoscopy (EGD) is performed frequently in patients with portal hypertension [6] because presence and size of esophageal varices correlate with severity of liver disease and determines the prognosis [7].

For patients who require a frequent EGD only for the surveillance of the esophagus, conventional EGD can be costly and inconvenient. Even for doctors, a heavy and bulky endoscopy system and sterilization equipment may be obstacles to accessibility. To ease this inconvenience, alternative modalities such as transnasal EGD [8,9] and esophageal capsule endoscopy [10 – 12] have been developed. Because transnasal EGD does not require sedation, time and costs are saved. However, problems related to poor image quality [13] and the need for a heavy endoscopy system remain unresolved. The protocol for esophageal capsule endoscopy is somewhat complicated [14], and controlling the capsule movement for visualization of the gastroesophageal junction is not possible.

To meet the requirement for a simple and easy modality for visualizing the esophagus, a disposable transnasal esophagoscope, the E.G. Scan, has been developed by IntroMedic Co. Ltd. (Seoul, Korea). Because this transnasal esophagoscope does not require either a large endoscopy system or special equipment for disinfection, it is portable and disposable. We conducted a pilot study of the first version of the E.G. Scan to evaluate its feasibility, safety, and tolerance in patients with suspected esophageal disease.

Case series

Device description

The E.G. Scan system consists of four main subsystems: a probe (containing the camera capsule, bending module, and data connector), a controller, a display system, and computer software (E. G. View) to display the images (**Fig. 1**). The connection tube, which does not have suction or an air channel, is 3.6 mm in diameter and the camera capsule at the tip head is 6 mm in diameter. The tip deflection capability is 60° up and 60° down. The camera capsule comprises four white light-

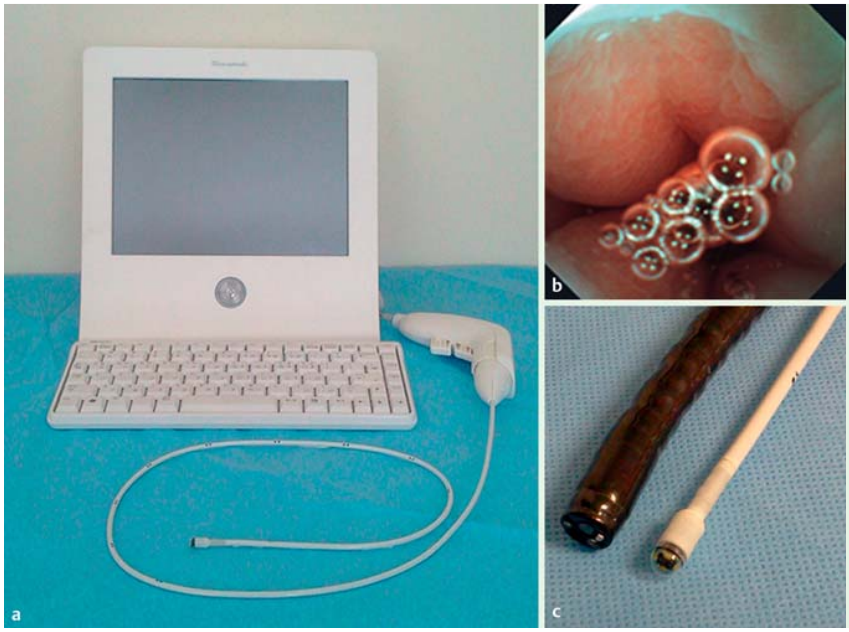

Fig. 1 E.G. Scan system. **a** E.G. Scan display system, controller, and probe. **b** E. G. View. **c** Relative diameters of two endoscopes, the E.G. Scan (6 mm) and a conventional endoscope (9.8 mm, GIF-H260, Olympus Optical, Ltd., Tokyo, Japan).

emitting diodes (LEDs) and a complementary metal-oxide semiconductor (CMOS), and has a field of view of 125° and a resolution of 400 × 400 pixels. The probe is made from human compliance plastics and sealed with a biocompatible adhesive, which are both designed for single use and therefore do not have to be disinfected. The controller has both freeze-capture buttons and an up – down lever at the handle. The display system consists of a liquid crystal display (LCD) monitor, keyboard, and display software (E.G. View) to allow playback and storage of images taken during the procedure; this system is light enough to carry.

Patients and procedures

A prospective study was conducted from October 2010 to February 2011 at Severance Hospital, Yonsei University College of Medicine, Seoul, Korea. Patients referred for the evaluation of esophageal diseases were enrolled in the study. Inclusion criteria were: age 20 years or older, reflux symptoms (heartburn, epigastric soreness, and/or regurgitation), non-cardiogenic chest pain, and known or suspected esophageal varices. Exclusion criteria included history or symptoms of severe rhinitis and sinusitis, acute respiratory inflammation at the time of examination, and known abnormal anatomy of the nasal cavity or nasopharynx. All patients provided written informed consent before enrollment, and the study received approval from the institution's ethics committee and the Korean Food and Drug Administration.

All endoscopy procedures were performed by one endoscopist (J. W.C.) who was experienced in conventional and transnasal EGD. Two gastroenterologists (J.W.C. and M.J.C.), who were experienced in EGD and capsule endoscopy, reviewed all of the selected images independently and reported their results.

Patients were instructed to fast for at least 3 hours prior to the procedure. For the procedure, patients were seated with their neck at a 30° angle, and Xylocaine 10 % Pump Spray (lidocaine hydrochloride 10 mg/dose; AstraZeneca, London, UK) was sprayed into the nasal cavity and oropharynx for topical anesthesia. The endoscope, moistened with Lidocaine HCL jelly 2 % (lidocaine hydrochloride 2 % 20 mg/mL; Arlico Pharm Co. Ltd., Seoul, Korea), was inserted under visual control through the nostril to the pharynx. No sedatives or antispasmodics were used during the procedure.

The operator recorded the success or failure of the procedure, the reason for failure, the number of insertion attempts, and the side effects of the procedure. The quality of endoscopic images was graded, based on visualization of the Z-line and air-bubble interference [14]. Any pathologic lesions were photographed and recorded on the case report form. After the procedure, patients completed a written questionnaire to assess their satisfaction with the E.G. Scan.

Results

A total of 50 patients (24 men and 26 women) were included, and the mean age was 48.7±14.4 years. A total of 42 patients had known or suspected GERD and eight had known or suspected esophageal varices.

A transnasal esophagoscopy was performed successfully using the E.G. Scan in 46 patients (92.0 %). In four patients (8.0 %), it was impossible to insert the endoscope through the nasal cavity. At least 75 % of the Z-line was visualized in 25 patients, and bubbles or saliva were controllable with sips of water in 42 of 46 patients (91.3 %). **Table 1** summarizes the technical characteris-

Table 1 Technical characteristics of the E.G. Scan (N = 50).

Technical characteristics	Patients, n (%)
Success rate of nasal intubation	46 (92)
Number of attempts at nasal intubation	
1	37 (74.0)
2	9 (18.0)
≥ 3	4 (8.0)
Z-line visualization (n = 46)	
100 %	8 (17.4)
≥ 75 %	17 (37.0)
50 % – 75 %	13 (28.3)
< 50 %	8 (17.4)
Interference by bubbles/saliva (n = 46)	
Controllable with sips of water	42 (91.3)
Uncontrollable with sips of water	4 (8.7)

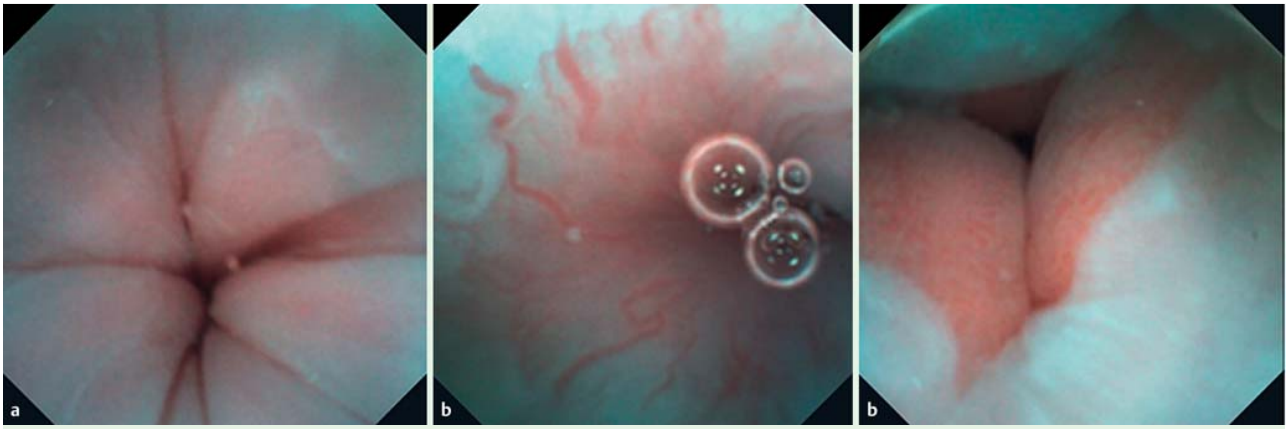

Fig. 2 Images of a normal esophagus and Z-line obtained using the E.G. Scan.

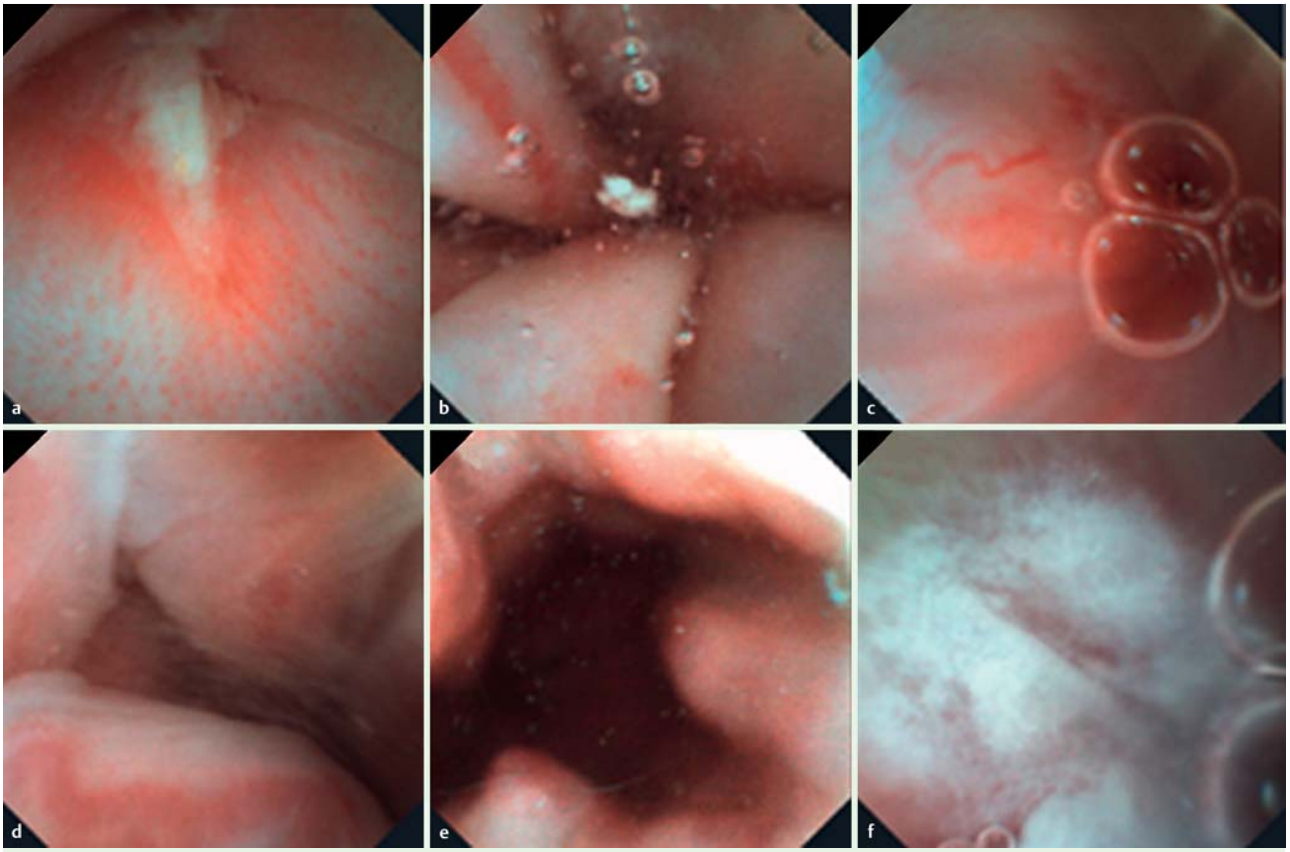

Fig. 3 Images of abnormal lesions taken with the E.G. Scan. **a, b** Erosive esophagitis. **c** Barrett's esophagus. **d, e** Esophageal varices. **f** Esophageal candidiasis.

tics using the E.G. Scan. **Fig. 2** shows images of a normal esophagus and gastroesophageal junction. Abnormal findings were identified in 27 of 46 patients (58.7%): erosive esophagitis in 18 patients (**Fig. 3a**, **Fig. 3b**) and Barrett's esophagus in one patient (**Fig. 3c**). In seven of the eight patients with liver cirrhosis, esophageal varices were noted (**Fig. 3d**,e). In one patient with sustained epigastric pain and dysphagia, esophageal candidiasis was observed (**Fig.3f**). No major complications including epistaxis, aspiration, or perforation were observed. Nasal introduction caused no or only mild pain in 32 of 46 patients (69.6%), and moderate pain in 14 of 46 patients (30.4%). The majority of patients did not experience nausea, sore throat, choking sensation, or weakness. Patient tolerance is summarized in **Table 2**.

Discussion

This study demonstrated that the first version of the E.G. Scan has the potential to be a diagnostic modality of choice for esophagoscopy in the near future. The E.G. Scan appeared to be well tolerated by almost all patients, and there were no major complications, including epistaxis, aspiration, or perforation. The E.G. Scan also allowed good visualization of the Z-line, leading to detection of erosive esophagitis and esophageal varices.

This novel, disposable, transnasal esophagoscope has the following advantages. First, transnasal introduction could minimize the gag reflex and vomiting, and thus sedation is not required [8], [9]. This ability could significantly decrease the additional risk of car-

Table 2 Assessment of patient tolerance.

Symptoms (n)	None	Mild	Moderate	Severe	Total
Epistaxis	46 (100 %)	0 (0 %)	0 (0 %)	0 (0 %)	46 (100 %)
Nasal pain	2 (4.3 %)	30 (65.2 %)	14 (30.4 %)	0 (0 %)	46 (100 %)
Nausea	13 (28.3 %)	23 (50.0 %)	10 (21.7 %)	0 (0 %)	46 (100 %)
Sore throat	20 (43.5 %)	16 (34.8 %)	10 (21.7 %)	0 (0 %)	46 (100 %)
Choking sensation	35 (76.1 %)	9 (19.6 %)	2 (4.3 %)	0 (0 %)	46 (100 %)

diopulmonary depression, and reduce the procedure and recovery times as well as the associated costs and loss of work productivity. Second, the E.G. Scan allows more efficient utilization of resources, thereby saving space, time, and running costs. Conventional endoscopy systems occupy a large amount of space, but the E.G. Scan has a compact display system consisting only of an LCD monitor and a keyboard. Another major advantage is that no disinfection is required because the probe is designed for single use and is disposable. The small size of the E.G. Scan system means that it can be used at the patient's bed side, in the doctor's office, and in emergency rooms. Use of this device in the emergency room would allow doctors to verify gastrointestinal problems among the causes of atypical chest pain, and also help them to rapidly decide if an urgent procedure is required to control upper gastrointestinal bleeding if suspected. The E.G. Scan can also be used to reduce the economic and medical burden of the patient when a second-look endoscopy is required after endoscopic interventions, such as esophageal variceal ligation or other endoscopic hemostasis, or to evaluate the response after anti-reflux therapy. In contrast to esophageal capsule endoscopy, the E.G. Scan probe can be maneuvered to allow adjustment of the perspective or angle, and the gastroesophageal junction can be observed without interrupting esophageal peristalsis. The endoscopist can also capture still images and record video at will, and can continue to observe until satisfied with the examination.

There are still some technical drawbacks associated with the E.G. Scan. There is no channel for air insufflation or water injection, so that the presence of bubbles, saliva, and secretions in the esophagus could potentially impair the quality of the images. The limited bending angle of the probe tip (only 120° up and down) also currently hampers very detailed observations. Passing the probe through the nose was difficult in some patients (8 %), particularly women, because of the small meatus of the nose. Finally, a conventional EGD may be required for confirmation of pathology and therapeutic intervention, because the E.G. Scan was developed only for diagnostic purposes and does not have a biopsy channel. These technical limitations should be improved in the future.

In summary, the E.G. Scan, which is a disposable transnasal esophagoscope, is feasible, safe, and well tolerated for the evaluation of esophageal diseases. Although this first version of the E.G. Scan has some technical limitations compared with conventional EGD, its convenience, good tolerance, rapid access, cost-effectiveness, and good safety profile indicate that it may be an acceptable alternative to conventional esophagoscopy for surveillance. Technical improvement of the E.G. Scan will contribute to the expansion of its use in clinical practice. The usefulness and diagnostic accuracy of the E.G. Scan for screening or diagnosing esophageal disease needs to be examined in more detail in future large-scale, prospective, comparative studies with conventional EGD.

Competing interests: None

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