Comparison of thin versus standard esophagogastroduodenoscopy

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KEY POINTS FOR CLINICIANS

- Most patients tolerate unsedated, ultrathin esophagogastroduodenoscopy (EGD).
- The recovery time is approximately halved for ultrathin unsedated EGDs.
- Patients undergoing unsedated EGD report more gagging and choking than do patients having the sedated examination.
- Patients receiving sedated upper endoscopy report more anxiety than those receiving an unsedated examination.
- Once credentialed in upper endoscopy, physicians do not require further training or skills to perform ultrathin EGD.

■ OBJECTIVE To compare the tolerance, feasibility, and safety of ultrathin esophagogastroduodenoscopy (EGD) in unsedated patients with conventional EGD in sedated patients.

■ STUDY DESIGN This was an unblinded, randomized controlled trial.

■ POPULATION Diagnostic EGD was performed on 72 adult outpatients at a US Air Force community hospital residency. Patients were randomized to either ultrathin or conventional EGD (n = 33 and 39, respectively).

■ OUTCOMES MEASURED Patients reported their tolerance of the procedure (pain, choking, gagging, and anxiety; scale 0–10), and the endoscopist reported the effectiveness of the procedure (successful intubation, reaching duodenum, retroflexion, and duration of examination and recovery) and safety (complications).

■ RESULTS No statistically significant difference was noted between the 2 groups in mean procedure time or pain during the procedure. Mean (± standard error) recovery time was approximately halved in the ultrathin group vs the conventional group (21.5 ± 2.3 min vs 55.4 ± 2.3 min, $P < .0001$). Although patients undergoing ultrathin EGD had higher mean gagging and choking scores, they had lower mean anxiety scores. Of 33 patients randomized to the unsedated ultrathin EGD procedure, 29 completed the protocol. The retroflexion maneuver was completed in 85% of patients in the ultrathin EGD group and 100% of patients in the conventional EGD group ($P = .017$). No statistically significant difference was noted between groups as to the likelihood of reaching the second portion of the duodenum (97% vs 100%).

■ CONCLUSIONS Most patients tolerate ultrathin EGD with significantly shorter recovery time and less overall anxiety than with the conventioanl procedure. Techniques to reduce gagging and choking associated with ultrathin EGD may improve patient acceptance and tolerability. Adoption of ultrathin EGD by primary care physicians may decrease cost, time, and inconvenience while increasing access to EGD for many patients.

■ KEY WORDS Endoscopy, gastrointestinal; randomized controlled trials; conscious sedation. (*J Fam Pract 2002; 51:625–629*)

Hacker et al[1] reported that 3 times as many patients prefer esophagogastroduodenoscopy (EGD) to upper gastrointestinal roentgenography. EGD is safe, with complication rates between 5 and 10 per 10,000 procedures.[2] However, only 2% of US family physicians perform upper endoscopy.[3]

In the United States, conventional EGD is usually performed under conscious sedation to reduce discomfort and anxiety.[4] Conscious sedation has potential negative aspects, including costs and side effects,[5] increased risks of respiratory depression,[2] and, very rarely, mortality.[5] Indirect costs related to lost work are unmeasured. All these factors may decrease patient tolerance or acceptance of conventional EGD with conscious sedation.

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In the last decade, an ultrathin (5.3–5.9 mm diameter) fiberoptic endoscope was developed. Shaker et al[6] used an ultrathin endoscope to perform transnasal endoscopy of the gastrointestinal tract. Since then, several prospective studies have evaluated ultrathin EGD.[7–9] One study compared ultrathin with conventional EGD, although both groups of subjects were unsedated.[10] Studies comparing EGD techniques were performed in large medical centers by gastroenterologists.[7–17] The purpose of this study was to assess the feasibility, safety, and patient tolerance of unsedated ultrathin EGD by generalists in a community setting.

METHODS

Outpatients (aged 20–80 years) from a US Air Force family practice residency were referred to a family practice endoscopist for further evaluation of dyspepsia, heartburn, and epigastric pain. Exclusion criteria included pregnancy, evidence of acute gastrointestinal hemorrhage, potential need for therapeutic endoscopy, a medically unstable patient (eg, recent myocardial infarction or stroke), coagulopathy, unstable angina, severe chronic obstructive pulmonary disease, and severe aortic stenosis. The local institutional review board approved the study.

An Olympus GIF-N230 gastrointestinal videoscope (Olympus America Inc, Melville, NY) with an outer diameter of 6.0 mm, an accessory channel of 2.0 mm, a working length of 122 cm, tip deflection of 180° (up and down) and 160° (right and left), with a field of view of 120° was used for the ultrathin procedures. An Olympus GIF-130 standard gastroscope (Olympus America Inc) with an outer diameter of 9.8 mm, an accessory channel of 2.8 mm, a working length of 103 cm, tip deflection of 210° up, 90° down, and 100° right and left, with a field of view of 120°, was used for the conventional procedures. Both endoscopes are forward-viewing (Figure 1).

After standard informed consent was obtained, the endoscopist made a phone call to access a computer-generated patient list for randomization. No patient withdrew after randomization. The endoscopist (T.W.) performed all endoscopies in the gastrointestinal suite with the patient in the left lateral position. An intravenous line was started and tetracaine 2% was sprayed in the posterior pharynx; pulse oximetry, cardiac monitoring, and verbal reassurance by the endoscopist were provided to patients in both groups. Sedation was slowly titrated in increments of 25 mg meperidine (or 50 mg fentanyl if the patient was allergic to meperidine) and 0.5 mg midazolam until a suitable level of sedation was obtained for endoscopy. Biopsy samples were obtained when indicated. Patients who were unable to tolerate the unsedated examination were given intravenous sedation, and the examination was completed using ultrathin EGD.

Upon discharge from the recovery area, all patients completed a questionnaire regarding their tolerance of the procedure. Patients completed 10-point visual scales indicating pain, choking, gagging, and anxiety both during the insertion of the endoscope and for the remainder of the examination. Patients were asked if they would choose to have the procedure again if endoscopy were indicated in the future. After the procedure, the endoscopist completed a questionnaire assessing the completeness of the examination (eg, whether the endoscope was advanced to the second portion of the duodenum and retroflexion was performed). Indications for the procedure, demographics, clinical findings, complications, the duration of the examination, and recovery duration were noted.

This study was planned to achieve a power of 0.80 to detect changes of 2.0 on tolerance scores between the study groups. Statistical analyses included the independent *t*-test, Fisher exact test, Mann-Whitney *U* test, and chi-square test. Multivariate regression analysis and analysis of variance were used to assess the effect that sex may have had on patients' tolerance scores. Analysis was by intention to treat.

RESULTS

Of 80 outpatients eligible for the study, 8 (10%) declined entry before randomization. Of 72 remaining, 33 were randomized to ultrathin EGD and 39 to the conventional procedure. The 2 groups were evenly matched for age, race, body mass index (BMI), indication, and EGD findings (Tables 1 and 2). There were more women in the conventional group (80% vs 55%, $P = .041$; Table 1).

During endoscope insertion, patients undergoing ultrathin EGD had higher mean gagging and chok-

TABLE 1

Patient demographics

Characteristic	Ultrathin EGD (n = 33)	Conventional EGD (n = 39)	*P*
Age, y (mean ± SE)	49.8 ± 2.9	46.9 ± 2.2	.406
Female (%)	55	80	.041
Race (%)			
Caucasian	67	44	.123
African American	27	39	
Other	6	18	
Body mass index (mean ± SE)	28.8 ± 0.88	28.7 ± 0.81	.966

EGD, esophagogastroduodenoscopy; SE, standard error.

TABLE 2

Indications and esophagogastroduodenoscopy findings

	Ultrathin EGD	Conventional EGD	*P*
Indications, n (%)			
GERD	26 (79)	22 (56)	.050
Abdominal pain	9 (27)	18 (46)	.143
Dyspepsia	2 (6)	7 (18)	.166
EGD findings, n (%)			
Esophagitis	9 (27)	6 (15)	.254
Hiatal hernia	15 (45)	13 (33)	.338
Gastritis	20 (61)	29 (74)	.310
Gastric ulcer	1 (3)	4 (10)	.366
Duodenal ulcer	0	0	
CLO test positive	4 (13)	11 (28)	.150
Patient tolerance, score (mean ± SE)			
During insertion			
Anxiety	3.2 ± 0.47	5.7 ± 0.45	<.0001
Pain	2.0 ± 0.34	1.4 ± 0.29	.574
Choking	3.0 ± 0.42	1.0 ± 0.32	.022
Gagging	4.2 ± 0.45	1.3 ± 0.34	<.0001
During procedure			
Anxiety	3.1 ± 0.48	2.5 ± 0.43	.350
Pain	1.3 ± 0.31	1.2 ± 0.27	.771
Choking	1.7 ± 0.33	1.0 ± 0.25	.081
Gagging	2.4 ± 0.35	1.2 ± 0.28	.007
Technical aspects of procedure			
To second portion of duodenum (%)	97	100	.458
Retroflexed (%)	85	100	.017
Duration of examination, min (mean ± SE)	18.2 ± 0.93	17.5 ± 1.1	.632
Duration of recovery, min (mean ± SE)	21.5 ± 2.3	55.4 ± 2.3	<.0001

EGD, esophagogastroduodenoscopy; GERD, gastroesophageal reflux disease; SE, standard error.

ing scores, but lower anxiety scores. For the remainder of the procedure, ultrathin EGD patients had higher gagging scores but no statistically significant differences were noted between groups for pain, choking, or anxiety (Table 2). Twenty-nine patients (88%) assigned to the ultrathin EGD group completed the unsedated examination, and 32 (97%) were willing to repeat an unsedated procedure with the ultrathin endoscope in the future. The mean (± standard error) dose of meperidine was 48.8 ± 2.3 mg; 2 patients required fentanyl 62.5 ± 12.5 mg and midazolam 2.2 ± 0.1 mg. Of the 4 patients allocated to the ultrathin group, which required sedation, the mean dose of meperidine was 50 ± 0 mg and midazolam 2.8 ± 0.5 mg. The time required for sedation in the conventional group was 4.1 ± 0.6 min and in the ultrathin EGD group was 5.5 ± 0.5 min (P = .280).

The second portion of the duodenum was reached as often with the ultrathin endoscope as with the conventional apparatus (Table 2). However, retroflexion was achieved less often with ultrathin EGD than with conventional EGD (85% vs 100%, P = .017). Although examination times did not differ between groups, the recovery time was significantly shorter with ultrathin EGD (21.5 ± 2.3 min vs 55.4 ± 2.3 min, P < .0001). No complications were noted in either group. Analysis of variance and multiple regression analysis showed no statistically significant difference in the tolerance scores by sex.

DISCUSSION

We examined differences in patients' experiences during EGD when a relatively thin scope was used without sedation vs a conventional wider scope with sedation. We expected the ultrathin scope to be preferable to both patients and physicians because of the reduced risk and lower cost associated with an unsedated procedure performed in an outpatient setting.

This study has major implications for family physicians. First, ultrathin EGD requires less recovery time than the conventional procedure. In addition, unsedated endoscopy does not require continuous cardiopulmonary monitoring.[18] In contrast, conventional EGD generally requires a minimum of 2 support personnel: 1 to assist the endoscopist and 1 to monitor vital signs. A third assistant is occasionally needed to monitor patients in recovery. Ultrathin EGD requires only 1 assistant. A thorough exploration of cost savings associated with ultrathin EGD was beyond the scope of this study. A recent study[13] found that ultrathin EGD required less procedure time, less time in the procedure room, and less recovery time, with a cost savings of US $125 per procedure. Second, EGD is traditionally limited to being performed in gastrointestinal suites. Our find-

FIGURE 1

Ultrathin endoscope, GIF-N230 (left); standard endoscope, GIF-130 (right)

ings suggested that most patients can tolerate ultrathin EGD in an outpatient setting, thereby offering easier access to the procedure.

Increased gagging and choking associated with the ultrathin device suggests that its deployment will require techniques to reduce gagging. Transnasal upper endoscopy appears to cause less gagging and choking,[8,9,11,14–17,19] but has not been studied in the family practice setting. Other techniques to determine pharyngeal sensitivity are needed.[20,21] One study[10] found that ultrathin EGD was tolerated better than conventional EGD for unsedated examinations; investigators[22] identified younger age and higher levels of pre-endoscopic anxiety as predictors of patient intolerance of unsedated endoscopy.

Although the success rate of retroflexion and duodenal intubation has not been reported in other studies[6–9,11,12,14–17,19,23] of ultrathin EGD, we could not perform retroflexion in 15% of subjects in the ultrathin EGD group. Inability to retroflex was secondary to patient intolerance and increased instrument flexibility. In these patients, the endoscopist might switch to a normal diameter scope; however, in a large national study using a standard diameter endoscope, retroflexion was not performed in 7% of patients.[24] The most frequent contribution of retroflexion is the identification of a dysfunctional lower esophageal sphincter. In our experience, a small fundal polyp and a large diverticulum in the cardia would be missed in the absence of this maneuver. In contrast, we were unable to intubate the duodenum in 3% of patients undergoing ultrathin EGD. Rodney and colleagues[24] cited in their national study that with use of the standard endoscope, duodenal intubation was not achieved in 7% of patients. With increased experience with the ultrathin device, endoscopists may be able to develop techniques to overcome the increased flexibility (eg, using the biopsy forceps in the accessory channel to increase rigidity).

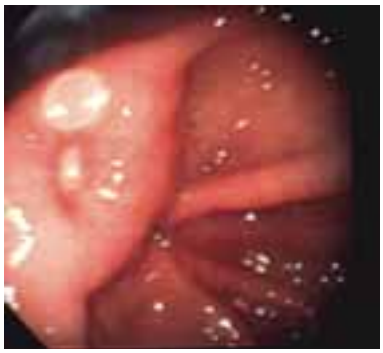
Although we found no significant differences in the proportion of clinical findings between the 2 groups, the findings may have been different had we been able to retroflex the scope in the ultrathin EGD group. The diagnostic accuracy,[11,17] image quality,[11,23] and adequacy of the smaller biopsy specimen for pathologic diagnosis[9,25,26] for ultrathin EGD have been reviewed and consistently determined to be clinically acceptable. Image quality of the 2 techniques is comparable (Figure 2). Although the biopsy specimens obtained with the ultrathin endoscope were smaller than samples of tissue obtained with the conventional device, CLO test positivity did not differ between the groups.

Conventional EGD required more recovery time and was associated with significantly higher anxiety. It is possible that the relatively higher anxiety experienced by patients in the conventional EGD group can be explained by fear of loss of control, fear

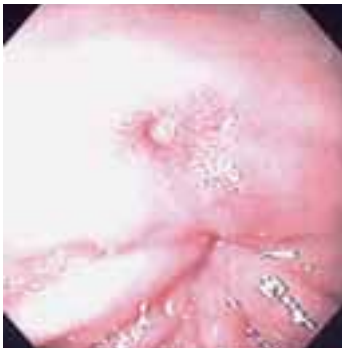
FIGURE 2

View of gastric ulcer with GIF-N230 (A) and GIF-130 (B)

A



B



about risks related to sedation, or a combination of psychosocial factors. One limitation in the conventional EGD group was the potential bias of the sedation when patients responded to the postrecovery surveys. Future studies may control for this sedation-effect bias by repeated measures over a period of a few days. Another limitation of our study was that the verbal reassurance offered to patients before and during endoscopy was nonscripted and may have influenced tolerance scores. A third limitation was that the patient questionnaire was given to patients by the endoscopist, thereby possibly introducing a social desirability bias. Finally, the small sample size limited the ability to detect differences that may be clinically meaningful.

Ultrathin EGD costs less, provides similar results, and has acceptable tolerability compared with conventional EGD. Once they are EGD credentialed, clinicians do not require further training or skills to perform the procedure with the ultrathin device. As more family physicians feel comfortable performing EGD in an outpatient setting, more patients will have access to this important procedure.

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