Sedationless Upper Endoscopy

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The use of sedation with peroral passage of conventionally sized endoscopes for upper endoscopy is the standard practice for most endoscopists in the United States. The administration of sedatives requires time-consuming and resource-intensive patient monitoring, has substantial cost, and can produce side effects and rare complications. Ultra-thin videoendoscopes (outer diameter less than 6 mm) have been developed, can easily be passed transorally or transnasally without sedation, and have been shown to be well tolerated and accurate. Unsedated upper endoscopy can provide an efficient, cost-effective alternative to standard endoscopy, should be useful for endoscopic screening, and can be offered as an option to conventional sedated examination. [Rev Gastroenterol Disord. 2006;6(1):13-21]

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Key words: Endoscopy • Unsedated • Sedationless • Ultra-thin • Ultra-slim • Small-caliber • Esophagoscopy • Esophagastroduodenoscopy

Diagnostic, as well as therapeutic, upper endoscopy has traditionally been performed with the aid of intravenous narcotics and benzodiazepines. Although these medications have a fairly rapid onset of action, the pre-procedural preparation time, administration time, and post-procedure recovery time required for sedation adds substantial cost to the performance of endoscopic procedures. Moreover, despite their excellent safety profile, these sedative medications are still responsible for much of the morbidity and mortality associated with endoscopic procedures. Sedationless upper endoscopy is clearly a desirable goal because it can decrease cost, increase efficiency, and avoid sedation-related complications.

The major advance in technology that has spurred investigations into the performance of upper endoscopy without sedation has been the development of
narrow caliber endoscopes. Despite the availability of these instruments, the practice of sedationless upper endoscopy has had limited acceptance in the United States. In contrast, the use of propofol sedation, which increases the efficiency of endoscopy but does not improve safety and even adds cost, has become rapidly popular. This article will critically review the medical literature with the goal of identifying the advantages and limitations of the practice of upper endoscopy without sedation.

**Methods**

A review of all published English literature related to sedationless upper endoscopy was performed. The strategy consisted of a Medline search of articles from January 1966 to December 2005 using the key words “sedationless,” “small-caliber,” “ultra-thin,” and “unsedated.” Only publications that were directly pertinent to esophagoscopy or esophagogastroduodenoscopy (EGD) were included. Table 1

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Major studies assessing various aspects of unsedated upper endoscopy, such as feasibility, safety, adequacy, and cost-effectiveness are listed. The study design and patient populations are provided to highlight the randomized controlled trials (RCT). The other prospective studies were not carried out in a randomized controlled fashion. EGD, esophagogastroduodenoscopy; sc, small-caliber; sed, sedated.

Adapted with permission from Sorbi D, Chak A.
summarizes and outlines the studies from those articles that contained over 50 patients.\textsuperscript{2} 

**Instrumentation and Technique**

The development of small-caliber diameter endoscopes (Figure 1) has permitted the performance of unsedated upper endoscopy wherein the instrument is passed via the transoral or transnasal route. For comfortable transnasal passage of an endoscope, it should have an outer diameter (OD) of 6 mm or less. Endoscopes that have been created in this "slim" category can vary in these characteristics: caliber or OD, presence or not of an instrument channel, presence or not of left/right control knob and articulation, depth of field, field of view, working insertion length, and tip of instrument angulation. Some of these endoscopes were intended to be used for screening esophagoscopy, and their shorter length, thinner OD, and lack of biopsy channel limit their abilities to carry out full upper endoscopic surveillance. However, they are useful for the efficient screening of erosive esophagitis, Barrett’s esophagus, or esophageal varices. Other endoscopes have been designed to allow for complete EGD with a longer working length, stiffer insertion tube, and an accessory channel for biopsy of tissue, if needed. The trade-off is generally between the instrument’s OD size and desired features, with left/right control frequently sacrificed to preserve a slim profile and biopsy channel. These ultra-thin endoscopes have continued to evolve, and the currently marketed instruments are all videendoscopes containing a 2 mm accessory channel. These are listed with their technical specifications in Table 2.\textsuperscript{2}

Transnasal passage of the small-caliber videendoscope requires careful technique with special attention to educating, preparing, and reassuring the patient undergoing this procedure. Once fully informed and consented, the patient is usually prepared with an application of a topical anesthetic to the nasal passage and pharynx. Some endoscopists prefer the patient to be in an upright sitting position, whereas others perform the examination with the subject in the left lateral decubitus position. The patient can assist in the choice of nostril to intubate by occluding first one and then the other nostril while inhaling with a closed mouth, and selecting the side (if there is a difference) that seems most comfortable.

![Figure 1. Small-caliber upper endoscope. The distal ends of a small-caliber and a conventional esophagogastroduodenoscope are shown (A) along with the handle of the small-caliber endoscope (B).](image)

<table>
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<th>Olympus GIF-XP160</th>
<th>Fujinon EG-270N5</th>
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U/D, up/down; R/L, right/left.
Adapted with permission from Sorbi D, Chak A.\textsuperscript{2}
Sedationless Upper Endoscopy continued

In our experience, patients seem to relax more easily for the subsequent passage of the endoscope after seeing and experiencing the passage of the cotton swab to the back of the nose.

Endoscopists now available. The endoscope is inserted into the selected nostril and directed through the nasal passage to the posterior pharynx. From that point onward, the examination is performed like a regular upper gastrointestinal (GI) examination.

In order to minimize discomfort, it is critical to make only gentle and slow advances of the endoscope, paying attention to the location of the insertion tube in the nostril. It is important to engage the patient in a dialogue throughout the procedure to address any concerns and reduce anxiety. The patient may feel the air insufflation, which should be minimized, and may be sensitive to the torqueing and movement of the endoscope. Endoscopes that lack a left/right control knob and articulation depend upon torque of the instrument shaft for maneuvering. In general, the combination of up/down knob control and instrument shaft torque can place the instrument tip in the required positions to completely assess the upper GI tract. Most patients are interested in following the procedure on the video monitor, and tolerate the instrument passage very well. Some patients may not tolerate transnasal endoscope passage due to anatomical reasons, or may prefer to have the instrument passed transorally. In that case, topical oropharyngeal anesthetic can be used, with subsequent introduction of the instrument in the standard fashion of conventional endoscopy. Again, all movements of the instrument should be gentle and slow, in order to minimize a potential gagging reflex. Following the endoscopic procedure, the patient needs no recovery from sedation, and can immediately discuss the findings and management plans with the endoscopist.

If needed, biopsy specimens can be obtained during the upper endoscopy with a small flexible “pediatric” forceps if the endoscope contains an accessory channel. These biopsies, although smaller in size than those from conventionally sized forceps, are useful for confirming the suspicion of intestinal metaplasia or for other diagnostic purposes. The accessory channel makes the slim-caliber endoscope useful for certain therapeutic procedures, as evidenced by a recent report of successful unsedated, transnasal percutaneous endoscopic gastrostomy (PEG) in 12 patients in whom oral access to the esophagus was not possible. These 12 patients (accounting for 8% of all PEGs in that institution over a 27-month study period) underwent unsedated transnasal procedures due to their anatomical and general clinical conditions. The endoscopists used a 5.9-mm OD videoscope (GIF-XP160, Olympus Optical Co., Tokyo, Japan) with a 2-mm accessory channel, employing the pull-gastrostomy technique with a 16-Fr PEG tube incorporating a collapsible bumper. This experience confirms an earlier report of successful unsedated transnasal PEG placement in 21 of 23 patients using the same slim-diameter videendoscope, in which the 2 unsuccessful attempts were related to an inability to effectively transilluminate the abdominal wall. The high rate of success in these 2 reports likely relates to the use of the slim-caliber endoscope, in contrast to the significant failure rate (50%) in a previous experience using a 7.9-mm OD endoscope. Successful transnasal, unsedated endoscopic enteral feeding-tube placement has also been described using small-caliber endoscopes, comparing favorably to the transoral endoscopic approach or traditional fluoroscopic techniques.

Esophagoscopy

Upper endoscopes have traditionally had a 100-cm long shaft to enable duodenal intubation. When sedation is used for an upper tract examination, most endoscopists perform a complete EGD. Early studies on unsedated transnasal endoscopy demonstrated its utility in esophageal diseases. In these published reports, although the stomach and duodenum was also examined, the primary indication was screening for Barrett’s esophagus in patients with reflux symptoms or screening for varices in patients with cirrhosis. This led to
the concept of performing an unsedated examination that was limited to the esophagus in selected patients. The advantage is that the procedure can be performed more quickly than a complete EGD and one can consider the use of shorter narrower endoscopes without an accessory channel.

Ultra-thin endoscopes with a 3 mm to 4 mm diameter and a working length of up to 60 cm have been developed and tested for esophagoscopy. Examination with ultra-thin, stand-alone, battery-powered, fiberoptic esophagoscopes proved feasible, but technically inferior, for identifying esophageal pathology. New video esophagoscopes with a 4-mm diameter appear to be equivalent to regular endoscopes (see Figure 2) for identifying esophageal pathology. The major advantage to these instruments is that the examination can be performed quickly, limiting patient discomfort. The other advantage is that compared to EGD, esophagoscopy is technically easy. Numerous reports have been published by primary care practitioners as well as otolaryngologists on the performance of unsedated esophagoscopy, enabling the identification of esophagitis and Barrett’s esophagus in patients with reflux symptoms. The disadvantage to this approach is that a biopsy cannot be obtained if pathology is identified. However, the argument for not being concerned about biopsy capability is that a jumbo biopsy obtained during a subsequent sedated examination of those identified with Barrett’s esophagus as viewed by the small-caliber esophagogastroduodenoscope is shown.

Figure 2. Image quality. The endoscopic image of the squamocolumnar junction of the esophagus as viewed by the small-caliber esophagogastroduodenoscope is shown.

patients with gastroesophageal reflux symptoms for Barrett’s esophagus and screening cirrhotic patients for esophageal varices.

Feasibility, Tolerance, and Acceptance of Unsedated Transnasal and Peroral Endoscopy

Not all patients, especially in the United States, are willing to undergo an unsedated upper endoscopy and, even when an unsedated examination is performed, it cannot be completed in a proportion of patients. Although the reason is not noted and many patients may simply refuse to participate in any study simply because it is research, most studies on unsedated endoscopy demonstrated the feasibility of unsedated endoscopy. A randomized trial of unsedated small-caliber peroral EGD versus sedated, conventional EGD in a US Air Force community reported that 29 of 33 (88%) patients randomized to the unsedated arm could complete the examination. Another controlled study found that peroral unsedated EGD could be completed in 98% of 163 patients examined with a 6-mm endoscope, compared to 91% of 159 patients examined with a 9.8-mm gastroscope. Failure to complete a peroral EGD without sedation has been associated with larger scope diameter (>9 mm), pre-procedure anxiety, and younger age.

The smaller caliber of instruments used for unsedated examination makes it possible to consider a transnasal approach to upper GI tract examination. Avoiding the tongue and the uvula during intubation can minimize gagging and retching, but at the cost of nasal pain and epistaxis risk. An early report using a 5.3-mm instrument demonstrated the feasibility of transnasal intubation even in 15 cirrhotic patients, of whom 1 developed epistaxis. The results of early studies comparing transnasal and peroral approaches to intubation were difficult to interpret because many of the studies used smaller caliber instruments for the transnasal intubation and larger instruments for the peroral examination. The first prospective, randomized, crossover study comparing the 2 approaches with the same small-caliber instrument found that the transnasal approach was successful in 25 of 29 (86%) patients, compared to 34 of 35 (97%) patients undergoing the peroral approach, including 4 who were crossed over. Other studies performed transnasal endoscopy in 50 or more patients report a failure rate of 3% to 8% with the transnasal approach, generally because of tight
nasal passages, especially with a 6-mm instrument. Efforts to push across tight nasal passages cause significant pain\textsuperscript{15,30-32} when performing transnasal endoscopy. This route is also associated with epistaxis in up to 6\% of patients.\textsuperscript{30,32} The advantage to the transnasal route is less gagging\textsuperscript{15,30-32} and perhaps better tolerance of the examination once the nasal passage is traversed. Presumably, the use of 4 mm or 5 mm instruments without an accessory channel can improve the rate of success with the transnasal approach, albeit at the risk of limiting or losing the ability to obtain a biopsy.

Tolerance of unsedated examination with smaller caliber instruments has also been compared to sedated examination with standard-caliber endoscopes. This comparison is somewhat artificial because of the amnesia caused by benzodiazepines. It is not surprising that nearly all studies show that patients undergoing a sedated examination experience less discomfort, and that sedation enables endoscopy in patients who cannot tolerate an unsedated endoscopy.

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Acceptance of unsedated endoscopy by physicians and patients may be the biggest barrier to the wider adoption of this approach.\textsuperscript{1} Acceptance is indirectly measured in studies as the willingness to repeat the examination. Studies that have looked at this question report widely variable results and also report differences in preference between the transnasal and peroral approach. A French study of more than 1000 patients reported that 95\% of patients who had an unsedated small-caliber transnasal EGD were willing to repeat, and 91\% of those who had a prior unsedated transoral examination preferred the transnasal route.\textsuperscript{29} In contrast, a Canadian study found the willingness to repeat only 65\% with an unsedated approach, compared to 81\% with sedation.\textsuperscript{26} Some studies\textsuperscript{20,21} have found that patients who had transnasal esophagoscopy were less likely to prefer an unsedated procedure compared to those who had peroral esophagoscopy. Others\textsuperscript{22,30} have reported that the transnasal approach is better accepted and may be equivalent to a sedated examination. These differences likely represent differences in methodology and in the study populations.

Accuracy

The accuracy of small-caliber endoscopes is typically related to their image quality, which is in turn related to the ability of the instrument to insufflate, clear the lens, and suction fluids, mucous or debris. The currently available instruments vary in their technical characteristics (see Table 2), however, the underlying premise is that small-caliber endoscopes will provide image quality and instrument maneuverability that can replicate that which is available from conventionally sized devices. As noted above, all of the currently marketed instruments are videoendoscopes and incorporate air/water/suction controls and a 2-mm accessory channel. However, the narrow lumen of the accessory channel can limit the ability to quickly and adequately suction thick secretions, blood or debris, and may compromise the adequacy of the examination. Those instruments lacking the left/right directional control knob and articulation rely upon torque of the instrument shaft to place its tip into the required positions for complete inspection of the esophagus, stomach, and duodenum. This is sometimes technically challenging, and could compromise the quality of the examination. In contrast to the requirements of thin-caliber endoscopes designed for an abbreviated upper endoscopy in which screening the esophagus for Barrett’s mucosa, esophageal varices, or esophagitis is the goal, the challenges are different for the instruments designed to perform a complete examination of the upper GI tract. The data available from randomized, controlled, clinical trials for an analysis of endoscope accuracy are quite limited, whether for screening esophagoscopy or complete upper endoscopy.

One early comparison of the accuracy of a 6-mm OD videendoscope (XGIF-N200H, Olympus America Inc., Melville, NY) to a standard 9.5-mm OD videendoscope (GIF-100, Olympus America Inc., Melville, NY) was based on tandem endoscopic procedures performed by the same endoscopist.\textsuperscript{21} In this study, the instruments were passed transorally. An initial, unsedated, small-caliber endoscopy was followed by a sedated exam using the standard-sized instrument. The unsedated ultra-thin instrument exam missed 5 of 59 endoscopic findings: 3 hiatal hernias and 2 gastric erosions, yielding a sensitivity of 92\% and specificity of 100\%. In another prospective trial, patients underwent tandem upper endoscopic
examinations, first with unsedated endoscopy using a 5.3-mm OD (GIF-N30, Olympus America Inc., Melville, NY) instrument passed by one endoscopist followed by conventional sedated or unsedated endoscopy with a standard-caliber instrument passed by a second endoscopist, who was blinded to the results of the first procedure. In this study, the investigators report the sensitivity of transnasal endoscopy to be 89%, with a specificity of 97%, with 1 small nodule at the cardia and 1 subtle distal esophageal ring missed by the transnasal small-caliber instrument exam.

In a multiphased study involving volunteer subjects and patients undergoing unsedated and sedated small-caliber transoral EGD using a 6-mm OD videoendoscope (EG1840, Pentax Precision Instrument Co., Orangeburg, NY) compared to sedated conventional endoscopy using standard-sized instruments (GIF-100 9.5-mm OD, GIF-Q140 10.5-mm OD, Olympus Corp., Tokyo, Japan), the small-caliber endoscope was determined to have an accuracy of 96% and 97%, sedated and unsedated, respectively. During the sedated small-caliber exams, 1 duodenal polyp and 1 anastomotic stricture requiring dilatation were missed. In the unsedated small-caliber series, prominent gastric vessels were not recognized.

The accuracy of an ultra-thin, 60-cm, working-length, battery-powered esophagoscope (XEF-DP, 3.1-mm OD, Olympus Corp., Tokyo, Japan) has been reported, with a sensitivity for detecting Barrett’s esophagus, esophageal tumors, esophageal varices, and overall findings of 54.5%, 66.7%, 80%, and 61.3% respectively. Specificities for these same findings were 96.6%, 100%, 100%, and 96.8%, respectively. This same group of investigators subsequently reported their more encouraging experience using a 4-mm OD, battery-powered, fiberoptic esophagoscope (LF-GP, Olympus Corp., Tokyo, Japan) and a 4-mm OD videendoscope (XEF 1401, Olympus Corp., Tokyo, Japan) compared to a conventional endoscope (GIF-140, Olympus America Inc., Melville, NY) which was used transorally under sedation in tandem by the same endoscopist following the transoral or transnasal exam with the ultra-thin caliber endoscope. In this study, the overall sensitivity, specificity, and accuracy for all esophageal findings were 91%, 99%, and 98%, respectively. Missed lesions included mild esophagitis, a subtle distal esophageal ring, and a small hiatal hernia. Accuracy did not differ between the battery-powered instrument and the videoendoscope.

In a more recent report, further assessment was carried out on the 4-mm OD, 60-cm long videoendoscope described in the above study (XEF-140Y1, Olympus Corp., Tokyo, Japan), in which the slim instrument was passed without sedation transorally or transnasally and compared to conventional sedated peroral endoscopy employing a 9.8-mm OD videoendoscope (GIF-140, Olympus America, Melville, NY). With conventional endoscopy considered the gold standard, the diagnostic accuracy of unsedated transoral endoscopy was 95%, with a 95% confidence interval (CI) of 86% to 99%, and the diagnostic accuracy of unsedated transnasal endoscopy was 100% with a 95% CI of 92% to 100%. All lesions viewed during the conventional upper endoscopy were seen with the unsedated ultra-slim endoscope, and extra findings (2 hiatal hernias, 1 distal esophageal ring) discovered during unsedated exams, but not seen during conventional exams, were considered “false positives” for the analysis.

The accuracy of detecting esophageal varices in known cirrhotic patients with unsedated, small-caliber transnasal endoscopy was further established in a report of the use of a 5.3-mm OD endoscope (either FG16X [fiberoptic], EG-1540 [video] Pentax Precision Instruments, Orangeburg, NY, or GIF-N30 [fiberoptic], Olympus America, Melville, NY) in a tandem comparison with a conventional sedated endoscopy employing a 9.8-mm OD videoendoscope. All esophageal and gastric varices were detected with the small-caliber instruments (100% sensitivity, specificity, and accuracy) and there was complete agreement as to the size of the varices. One patient who had endoscopic evidence of portal hypertensive gastropathy on conventional endoscopy was missed by the transnasal exam. Otherwise, all lesions found by the conventional endoscope were seen with the 5.3-mm OD instruments.

This same group of investigators also reported on the accuracy of biopsies taken during unsedated, transnasal endoscopy to detect Barrett’s metaplasia and dysplasia, using these 5.3-mm OD endoscopes (FG16X, Pentax Precision Instrument Corp. Orangeburg, NY; or GIF-N130, Olympus America Inc., Melville, NY) compared to the standard-sized 9.8-mm OD endoscope (GIF-100 or GIF-140, Olympus America Inc., Melville, NY). Transnasal upper endoscopy detected Barrett’s metaplasia histopathologically in 31 of 32 patients. The level of agreement for the presence of dysplasia in biopsy specimens obtained between conventional upper endoscopy and transnasal upper endoscopy was excellent (k = .79). Interobserver agreement for dysplasia in specimens obtained by conventional upper endoscopy (k = .61) and by transnasal upper endoscopy (k = .61) was the same.
Conclusion

Endoscopic practice is under economic pressure. Sedationless endoscopy is an increasingly attractive option because it lowers cost, improves efficiency, and possibly adds safety. The technology to enable unsedated procedures such as smaller-caliber endoscopes, scopes with 1 directional tip deflection, and smaller charged-coupled devices continues to evolve. Numerous studies prove that motivated patients tolerate unsedated endoscopy, and the procedure is as accurate as sedated endoscopy. Unsedated esophagoscopy is also an emerging technique that can help screen for Barrett's esophagus and esophageal varices. Barriers to the widespread practice of unsedated upper endoscopy include physician as well as patient attitudes toward sedationless procedures. Educational efforts could improve the usefulness of this technique as new small-caliber, maneuverable endoscopes develop.

References


Main Points

- Sedationless upper endoscopy is clearly a desirable goal because it can decrease cost, increase efficiency, and avoid sedation-related complications.
- The development of small-caliber diameter endoscopes has permitted the performance of unsedated upper endoscopy wherein the instrument is passed via the transoral or transnasal route. For comfortable transnasal passage of an endoscope, it should have an outer diameter of 6 mm or less.
- New videoesophagoscopes with a 4-mm diameter appear to be equivalent to regular endoscopes for identifying esophageal pathology. The major advantage to these instruments is that the examination can be performed quickly, limiting patient discomfort.
- Clearly, the feasibility of an unsedated procedure in practice is closely linked to how well it is tolerated and accepted by patients and physicians.
- The accuracy of small-caliber endoscopes is typically related to their image quality, which is in turn related to the ability of the instrument to insufflate, clear the lens, and suction fluids, mucus, or debris. Currently available instruments vary in their technical characteristics, but the underlying premise is that small-caliber endoscopes will provide image quality and instrument maneuverability that can replicate that which is available from conventionally sized devices.


