Published in final edited form as:

Clin Gastroenterol Hepatol. 2014 May ; 12(5): 785–792. doi:10.1016/j.cgh.2013.10.014.

Development of a Program to train Physician Extenders to Perform Transnasal Esophagoscopy and Screen for Barrett's Esophagus'

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Abstract

Background & Aims—Screening for Barrett's esophagus (BE) and esophageal adenocarcinoma is not recommended because it was not found to be cost effective. However, physician extenders (PEs) are able to perform unsedated procedures—their involvement might reduce the costs of BE screening. We examined the feasibility of training PEs to independently perform transnasal esophagoscopy (TNE) and screen patients for Barrett's esophagus, and measured their learning curve.

Methods—Two PEs at a Veterans Administration (VA) medical center underwent a structured didactic training program and observed nasopharyngoscopies before performing TNE under the supervision of attending endoscopists. Individual technical and cognitive components of TNE were rated on a 9-point structured scale. Learning curves were constructed using cumulative summation. Once the PEs were judged to be technically competent, each PE performed 10 independent videotaped TNEs, which were graded.

Results—Both PEs identified anatomic landmarks after 18 consecutive procedures. PEs 1 and 2 performed satisfactory nasal intubations after 20 and 25 procedures and esophageal intubations

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DISCLOSURES: None of the authors have a conflict to disclose.

AUTHOR CONTRIBUTIONS: Bronia Alashkar (B, C, D, H), Ashley L. Faulx (A, B, C, E, G, I), Ashley Hepner (B), Richard Pulice (B), Srikrishna Vemana (B), Katarina B. Greer (B, C, E, F), Gerard A. Isenberg (A, E, G), Yngve Falck-Ytter (A, E, F, G), Amitabh Chak (A, B, C, D, E, G, I) A = study concept and design; B = acquisition of data; C = analysis and interpretation of data; D = drafting of the manuscript; E = critical revision of the manuscript for important intellectual content; F = statistical analysis; G = obtained funding; H = administrative, technical, or material support; I = study supervision

after 29 and 35 procedures, respectively. They acquired overall competence after supervised training on 43 and 47 procedures, respectively.

Conclusions—We developed a program at a VA medical center to train PEs to perform TNE to screen for BE. The PEs were able to perform TNE and recognize esophageal landmarks independently after a modest number of supervised procedures.

Keywords

CUSUM; esophageal cancer screening; prevention; cost reduction

INTRODUCTION

The incidence of esophageal adenocarcinoma has increased dramatically in the past several decades.¹ Over 9,000 cases are now diagnosed annually and the majority of these patients die within 5 years of diagnosis.² Barrett's esophagus (BE), a pre-malignant metaplastic condition with an 0.1 - 0.5% annual estimated risk of progression is the only known precursor of esophageal adenocarcinoma.³⁻⁹ Upper endoscopy (EGD) when performed in a subset of subjects with chronic gastroesophageal reflux disease (GERD) diagnoses Barrett's esophagus (BE) in about 10% of cases.^{3,10-12} Subsequent endoscopic surveillance of individuals diagnosed with BE is the current strategy for early detection of dysplasia/cancer and non-randomized investigations indicate that surveillance likely results in improved survival.¹³⁻¹⁷ However, because there is no randomized controlled trial to support its efficacy and EGD is expensive, endoscopic screening for BE is either not routinely recommended in all adult subjects with chronic GERD or is weakly recommended but only in adult subjects with multiple risk factors for esophageal adenocarcinoma.^{18,19} Thus, less than 5% of esophageal adenocarcinomas are diagnosed in individuals with previously detected BE.²⁰ Even if endoscopy was recommended in every adult with GERD symptoms, nearly 40% of adenocarcinomas occur in individuals without reflux symptoms.^{21,22} Clearly, the challenge is to develop new approaches for identifying Barrett's esophagus that are less expensive than EGD and can be widely adopted in the population at risk.

The need to use sedation prohibits the performance of EGD in the primary care setting, adds direct costs (medication administration, monitoring, personnel, and recovery time), adds indirect costs (day off work for patient as well as companion to drive patient home) and increases adverse events. Transnasal esophagoscopy (TNE) is as sensitive as EGD for identifying BE, is well tolerated and when performed, it avoids costs associated with sedation²³⁻²⁵. However, our survey of gastrointestinal endoscopists found that for a variety of reasons, including physician reluctance, unsedated TNE has not been widely accepted in the U.S.²⁶ Endoscopic procedures such as TNE offer the prospect of changing our current paradigm of BE screening. In a survey of primary care physicians, we found that although the majority replied that they did not recommend sedated EGD for chronic GERD symptoms, the availability of unsedated endoscopy within the primary care setting would lead to increased screening²⁷.

Up to 25% of asymptomatic male subjects older than 50 years at Veterans Affairs Medical Centers (VA) are reported to have BE.²⁸ Thus, the performance of sedated EGD for BE

screening even if EGD is performed only in patients with chronic GERD symptoms at VA medical centers with large demand for endoscopic services is challenging. The aim of this study was to determine whether it is feasible to train physician extenders (PEs), i. e., nurse practitioners and/or physician assistants to perform TNE in a VA. Training of PEs could then enable a new model for BE screening in outpatient primary care clinics in VA medical centers.

PATIENTS/MATERIALS AND METHODS

Setting

This study was performed in the Louis Stokes Wade Park VA Medical Center in Cleveland, OH within the endoscopy unit and primary outpatient clinics. The study was approved by the Louis Stokes Wade Park VA Medical Center, Institutional Review Board.

Training Program

Didactic training—Two PEs (1 PA and 1 NP) volunteered to learn TNE. They underwent one week of didactic structured training, which included four one hour lectures on techniques of TNE, normal anatomy, and diagnosis of BE and other esophageal pathology. PEs also read textbook chapters and reviewed videos on the basic anatomy and pathology of the oral and nasal cavity, hypopharynx, and the esophagus. This was followed by a 2 week period observing nasopharyngoscopy in the ENT clinic, to familiarize trainees with nasopharyngeal anatomy.

Procedural training—Hands-on TNE training was conducted under the supervision of any of four attending gastrointestinal endoscopists in two stages. In the initial stage, patients scheduled for standard sedated EGD were asked permission to perform a TNE while they were sedated. Trainees were instructed on nasal anatomy, pharyngoesophageal intubation, traversing the esophagus, and recognition of the gastroesophageal junctional anatomy. They were also taught to recognize nasal passages too tight for TNE and when to switch from a transnasal to a peroral approach. After the trainee reached a level of competence of performing TNE and identifying endoscopic landmarks without supervised instruction in at least 4 of 5 consecutive cases, they were then moved to the second stage in which they performed supervised unsedated TNE on consented volunteers prior to sedation for the standard EGD.

Independent phase—In the final independent phase, once the PEs were considered to have achieved competency (score > 7 for technical and cognitive components, see Competency Assessment section below) the trainees performed unsedated TNE in the clinic setting without supervision and the entire examination was videotaped. TNE examinations in this independent unsupervised phase were performed for screening and unlike the training phase these screened subjects did not have follow-up EGD unless suspected BE was identified during TNE. These procedures were not scored for the components of competency. The first 10 consecutive cases that the PEs performed without supervision were reviewed by an independent supervising physician (AC) who was blinded to the findings for accuracy of interpretation and completeness of the examination.

TNE Protocol

Patients with a history of recurrent epistaxis, altered nasopharyngeal anatomy, allergy to lidocaine derivatives, bleeding diathesis, or prolonged prothrombin time were excluded. TNE was performed with the TNE 5000 Esophagoscope available from Vision Sciences, Inc (Orangeburg, NY). This system has a disposable outer sheath that completely covers the endoscope. It also has a disposable channel for biopsies. The sheath allows sterile office based endoscopy without the need to disinfect the inner endoscope and therefore screening can be performed within the primary care clinic. Unsedated TNE was performed in the sitting position. The nasal passage with the wider patency was selected and anesthetized with an atomizer using a 1:1 mixture of 2% lidocaine and 1.0% neosynophrine instilled deep into the selected nares over a 2-minute period. A 3-second instillation of aerosolized 14% benzocaine into the oropharynx just prior to intubation was also used in some patients. Again, trainees were instructed to switch from a transnasal to peroral approach when the nasopharynx was too tight. Subjects who underwent TNE during the independent phase and were found to have suspected BE did not have biopsy attempted and were referred for standard sedated EGD. Biopsies were not performed as PEs often do not have privileges to perform biopsies.

Competency Assessment

Learning curves are based on defining objective thresholds of competency. Endoscopic learning can be broken into two components, technical competence and cognitive competence. The technical performance of TNE requires the passage of the scope through the nasopharynx and intubation of the esophagus. For TNE procedures the supervising physician scored the trainees' technical proficiency (Figure 1) in passing the endoscope through the nasopharynx and intubating the esophagus using a defined Likert scale of 1 to 9 (1 = novice, 9 = expert skill) after each procedure that the PE performed in the supervised training phase. We also monitored the frequency with which TNE was converted from the transnasal to peroral route. A rate less than 10% was considered acceptable. Technical competence was defined as a score of ≥ 7 for intubating the nasopharynx and intubating the esophagus in 90% of procedures. A competency threshold of 90% was selected based on studies of endoscopic learning, including a study we performed in colonoscopy learning and the American Society of Gastrointestinal Endoscopy's definitions of competence for basic endoscopic procedures.²⁹⁻³² The cognitive learning process for TNE consists of identifying specific landmarks that define the endoscopic presence of BE. These landmarks include the squamocolumnar junction, the top of the gastric folds, and the diaphragmatic pinch. The supervising physician noted whether the PE trainee was able to accurately identify each landmark with or without supervision (Figure 1). Cognitive competency was defined as the ability to identify each landmark without supervision (score of ≥ 7).

The supervising physician evaluator also rated overall performance of TNE by the trainee with a score of > 7 considered to be the threshold of competency.

Analysis

Trainees' technical learning curves for TNE were calculated in consecutive blocks of 5 procedures using the CUSUM (cumulative sum) method. One-way variance analysis was

used to compare success rates for successful intubation between consecutive blocks of 5 procedures. Trainees' cognitive learning curves were calculated using the same scoring system. Again, cognitive learning was calculated in blocks of 5 procedures and one-way variance was used to compare successful identification of all landmarks between consecutive blocks of 10 procedures.

RESULTS

Overall Competence

Trainers judged that PE1 and PE2 were able to perform independent TNE procedures and had achieved overall cognitive and technical competence after 44 and 47 supervised procedures, respectively (Figure 2). PE1 could not complete 1 procedure and PE2 could not complete 6 procedures during their supervised training. All PE1 procedures were performed transnasally whereas three PE2 procedures were changed from a transnasal to peroral route. Following the supervised training procedures both PEs performed 10 independent unsupervised procedures. All procedures were videotaped and reviewed by an attending gastroenterologist who confirmed the findings documented by the PEs.

Cognitive Competence

Both PEs were able to satisfactorily identify anatomic landmarks including GE junction, diaphragm, and top of gastric folds after 18 consecutive procedures performed on sedated patients (Table 1). Each trainee completed 10 TNE procedures in the unsupervised independent phase of the study. These procedures were videotaped and reviewed subsequently by an attending physician (AC). Both PE trainees were accurately able to identify anatomic landmarks independently. In addition, the trainees made a diagnosis of suspected Barrett's esophagus in 1, hiatal hernia in 3, and esophagitis in 6 of these cases. These diagnoses were confirmed upon review of the videotaped examinations. The Z line was completely visualized in 18 and partially visualized in 2 cases. Two individuals, 1 with severe esophagitis and 1 with suspected Barrett's esophagus, were referred for subsequent EGD.

Technical Competence

Nasal intubation and esophageal intubation were the two maneuvers that were technically most challenging when performing TNE. Intubation of the nasal cavity was learned more easily than intubation of the esophagus. PE1 performed nasal intubation satisfactorily after 20 supervised TNE procedures and PE2 performed nasal intubation satisfactorily after 25 supervised TNE procedures (Figure 3). PE1 had to perform 29 supervised TNE procedures before satisfactory performance of esophageal intubation and PE2 had to perform 35 supervised TNE procedures before satisfactory performance of esophageal intubation (Figure 4). The PE trainees each performed and completed 10 independent unsupervised procedures on unsedated study subjects. Aside from one episode of minor epistaxis, which ceased spontaneously there were no adverse events. The study subjects rated pain, gagging, and choking on a 9 point Likert scale (1 = minimal and 9 = severe). The median scores reported by patients after undergoing these procedures were 1 for each symptom. Sixteen, 17, and 17 subjects rated pain, gagging and choking at a score of 3 or less, respectively.

DISCUSSION

In order to propose screening for BE, the challenge is clearly to develop an approach that is less costly and safer than EGD. We chose to perform this study in the Wade Park VA Medical Center endoscopy suite and primary care clinic because this predominantly adult male population is at increased risk for BE. The training of non-physicians to perform TNE would also address the physician shortage within the VA medical system. We chose to train physician extenders (PEs), i.e. nurse practitioners and/or physician assistants, in the performance of TNE, a novel modality that is less expensive and invasive than standard EGD. The goal of this study was simply to determine whether PEs could be trained to perform TNE and define the training process required to achieve technical competency as well as cognitive competency in recognizing esophageal landmarks and BE.

The primary objective of our study was to determine the feasibility of training PEs to perform screening TNE examinations in a VA. We considered training primary care physicians but felt it would be more cost effective to train PEs. Given the time line and number of upper endoscopies performed in our VA and ability to get consent from subjects undergoing EGD, we found we were easily able to train 2 PEs who had other clinical responsibilities over the course of six to nine months, supervising each PE for one to two half days during a week. Our study demonstrates it may be feasible to consider a new model of screening for BE in VA hospitals. The use of unsedated TNE performed by PEs could not only reduce some of the demand for sedated EGD plus the cost of endoscopy, it would enable BE screening in a primary care setting, thus reaching a greater population of veterans who are at risk. Subjects identified with suspected BE could then be referred to gastrointestinal endoscopists for confirmation of BE by standard EGD and those with BE could be enrolled in surveillance programs.

There is clear precedent for nurse performance of screening and surveillance endoscopy procedures. Although nurses in the United States do not perform colonoscopies, other countries such as the United Kingdom have implemented nurse colonoscopy to decrease the cost of screening programs³³⁻³⁵. Nurses have also been trained to perform unsedated screening procedures such as flexible sigmoidoscopy³⁶. Therefore, it is natural to extend the concept of nurse performance of screening endoscopy to a new unsedated procedure such as TNE. This study demonstrates that training of non-physicians in TNE can be performed within a structured training program.

Measurement of learning is a subjective process. Using an objectively defined scale of competency, we made the assessment as quantitative as possible. The threshold of 90% accuracy compared to supervisor interpretation was based on our own study on acquiring endoscopic skills as well as in other studies of endoscopic learning. Cognitive skills for recognizing esophageal landmarks were attained fairly readily.

This training was sufficient to recognize esophagitis, hiatal hernias, and BE, and perform a screening examination. However, this training was not sufficient to recognize or manage more complex esophageal disorders. Thus, we would not expect the PEs to be competent nor would we recommend PE performed TNE in subjects suspected to have a subtle condition

such as eosinophilic esophagitis. Both PEs who volunteered for training had gastroenterology experience so they were familiar with esophageal diseases and Barrett's esophagus. The present research was not able to determine whether there is any difference in learning between PEs who work in internal medicine compared to those who work in gastroenterology, or even determine the variation in learning amongst PEs. One would have to train a far larger sample size to determine what factors are important for learning. The aim of this study was simply to demonstrate the feasibility of training PEs for BE screening.

The technical skills required to perform TNE took longer to attain than the cognitive skills required for recognizing esophageal landmarks. Esophageal intubation was more difficult to master than nasal intubation. Both of these skills and other technical aspects of performing TNE was satisfactorily and safely learned by both non-physicians within 50 supervised procedures. Following technical learning, the PEs were safely able to perform unsedated TNE procedures for screening. The subjects who underwent TNE procedures tolerated these procedures and did not report much greater discomfort than when TNE was performed by trained gastroenterologists.

The study was performed at a VA medical center and the results may not be representative of a more general population. TNE might prove more challenging in a younger population or a population with a greater proportion of women. However, the VA population does represent a population at increased risk for BE and is an appropriate population to develop a screening program.²⁸ Certain VA medical centers such as the one in which this study was performed have had to outsource endoscopic procedures because of a high demand for endoscopic services. The performance of TNE by non-physicians may help to meet some of this demand.

The objective of the study was to train PEs to examine the distal esophagus specifically so they would be able to recognize BE. They were not trained in other aspects of esophageal diseases. Independent TNE examinations that the PEs performed in this study and are currently performing are restricted to subjects with GERD without alarm symptoms. In most states, PEs need to practice under the supervision of a physician. The ability to videotape the TNE examinations for subsequent review allowed the attending physicians to ensure that the 20 independent examinations performed by the PEs were adequate and confirm the endoscopic diagnosis made by the PEs. Conceivably, in clinical practice, all non-physician TNE examinations could be videotaped and the adequacy of the examination confirmed by the supervising physician.

The results of this study should be interpreted within the limitations of the study design and the aim of the study. Training was limited to one nurse practitioner and one physician assistant who volunteered to learn TNE at a VA. These trainees were clearly motivated to learn TNE and had previous training in gastrointestinal diseases. Physician extenders without specific training may require a lot more training and it is possible that some will not be able to learn TNE. The small sample size limits generalizing these findings. The purpose of this study was simply to determine whether PEs could be trained to perform screening TNE. Although the grading scale for assessing the supervised phase of training was quantitative, interobserver agreement between the 4 graders could not be assessed. This

study only assessed ten independent TNE procedures for each PE so it cannot determine whether these PEs will be able to detect BE with the same sensitivity as gastroenterologists. We measured cognitive competency in identifying anatomical esophageal landmarks. However, other studies that have examined nurse performance of endoscopic procedures in clinical practice have found that nurses may actually perform a more careful inspection than physicians³⁷⁻³⁹. Therefore, it is reasonable to assume that nurse practitioners or physician assistants who perform TNE screening will perform a careful inspection of the esophagus for evidence of BE.

Cost of sedated EGD and accessibility have been two barriers to recommending screening for BE. This study suggests that it is feasible to propose a less expensive strategy for BE screening -- performance of unsedated TNE by non-physicians. Two trainees were able to master the skills of TNE and one is currently performing this unsedated procedure on patients seen in primary care clinics at the Cleveland Wade Park VA as part of a new BE screening program. Larger prospective studies will be required to determine whether trained PEs can effectively identify BE in such a screening program and whether screening will ultimately impact the early detection of esophageal adenocarcinoma. Despite numerous studies demonstrating that unsedated TNE is quite well tolerated, there are clearly other obstacles to acceptance of unsedated endoscopy such as physician and patient attitudes²⁶. The performance of TNE procedures by nurse practitioners or physician's assistants in an office setting could also help change the perception of primary care physicians and patients.

Acknowledgments

Grant support: This work was supported by the U.S. Public Health Service research grants RC4 DK090645 from the National Institute of Diabetes and Digestive and Kidney Diseases and U54 CA163060 and P50 CA150964 from the National Cancer Institute.

ABBREVIATIONS

BE	Barrett's esophagus
EGD	esophagogastroduodenoscopy
GERD	gastroesophageal reflux disease
NP	nurse practitioner
PA	physician's assistant
TNE	transnasal endoscopy
VA	Veterans Affairs

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Technical								
Passes instrument from oral cavity to hypopharynx								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Intubates the esophagus								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Maintains view of the GE junction								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Cognitive								
Recognizes diaphragm								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Recognizes top of gastric folds								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Recognizes squamocolumnar junction								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Recognizes abnormalities								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	
Overall assessment of performance								
☐	☐	☐	☐	☐	☐	☐	☐	☐
1	2	3	4	5	6	7	8	9
Instructor Required			Satisfactory (Minimal Instruction)				Outstanding (Independent)	

Figure 1.
TNE procedure evaluation form

Figure 2.
Learning curves assessing overall competence in performing TNE

Figure 3.
Learning curve assessing competence in nasal intubation

Figure 4.
Learning curves assessing competence in esophageal intubation

Table 1

Number of successive procedures completed per physician extender (PE) to demonstrate competency in specific skills

<i>Skill Acquired</i>	<i>PE1</i>	<i>PE2</i>
Identify Landmarks *	18	18
Nasal and oral cavity intubation	20	25
Esophageal intubation	29	35
Perform TNE independently	43	47

* Landmarks relevant to a procedural skill include identification of gastroesophageal junction (GEJ), hiatal hernia (HH) and gastric folds