

Safety of flexible endoscopic evaluation of swallowing examination in gastroenterological practice

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ABSTRACT

Background/Aims: In South Korea, the flexible endoscopic evaluation of swallowing (FEES) has been increasingly performed by gastroenterologists. The principal concern was the safety of the FEES performed by gastroenterologists without any involvement of speech-language pathologists. We aimed to characterize the safety and tolerance of gastroenterologist-directed FEES examinations (GDFEES).

Materials and Methods: We evaluated the GDFEES failures, safety profile (laryngospasm, epistaxis, vasovagal syncope, airway compromise, heart rate, blood pressure, and significant change in cardiovascular function), and discomfort level in patients undergoing GDFEES. These outcomes were also analyzed based on gender, age, and calendar period.

Results: A total 303 examinations in 268 adult patients with dysphagia were performed during the study period. The GDFEES failures occurred in 5 patients (1.7%). The causes of failures were poor co-operation and insertion difficulty. There were no instances of laryngospasm or vasovagal syncope or significant cardiovascular changes in any of the examinations. Self-limiting epistaxis occurred in 22 examinations (7.3%). The discomfort ratings were as follows: 128 examinations (43.0%) rated the overall discomfort of the test as none, 150 (50.3%) as mild, 18 (6.0%) as moderate, and 2 (0.7%) as severe discomfort. The discomfort level was significantly different only between the first and second half periods ($p < 0.001$), but it was related to neither gender nor age.

Conclusion: The GDFEES can be endorsed as an appropriate paradigm for clinical practice based on our study investigating its safety and tolerance.

Keywords: Complications, deglutition disorders, endoscopy, gastroenterologists, safety

INTRODUCTION

Langmore et al. (1) reported the first use of flexible laryngoscope for assessing dysphagia, termed flexible endoscopic evaluation of swallowing (FEES). The FEES examination allows for the prompt use of portable instrumentation to assess swallowing function in the clinic or at the patient's bedside (2). This procedure has been administered by speech-language pathologists (SLPs) with expertise in dysphagia and specialized training in fiberoptic endoscopy (3). The overall complication risk of this examination has been reported to be minimal (4-6).

Several rationales exist for the FEES examination in our gastroenterology practice. First, the limited availability of qualified SLPs is an important challenge for FEES delivery in South Korea. This challenge may grow in importance with the aging of our population, as the elderly are expected to experience increasing need for FEES examination. Second, gastroenterologists have been paying attention to identification of benign and malignant lesions in the laryngopharynx and upper esophagus in dysphagic patients. Frequent encounters between gastroenterologists and

dysphagic patients are also leading to growing interest for etiological diagnosis of dysphagic patients, especially since the advent of high-resolution impedance manometry examination for the diagnosis of oropharyngeal dysphagia as well as esophageal dysphagia (7-9). Finally, a few certified gastroenterologists are familiar with the use of transnasal endoscopy (TNE), well trained in the signs and symptoms of adverse reactions during endoscopic examination and are ready to take appropriate action if any complication occurs. Quite low cost of the endoscopic procedure in South Korea might be also affecting the acceptance of gastroenterologists-directed FEES (10).

In our previous study reporting the diagnostic performance between FEES and videofluoroscopic swallowing study, the results obtained with both tests correlated well in the detection of pharyngeal residue, penetration, and aspiration (11). To date, no study has examined the safety and tolerance of FEES in a gastroenterology practice without any involvement of SLPs. Therefore, we aimed to evaluate the safety and tolerance of gastroenterologist-directed FEES (GDFEES).

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MATERIALS AND METHODS

Subjects

We retrospectively reviewed a total of 303 GDFEES examinations in 268 adult patients with oropharyngeal dysphagia (OPD). This study included consecutive patients with OPD undergoing GDFEES between December 2011 and July 2014. The OPD diagnosis was made after a review of clinical history with regard to difficulty at swallowing food or pills, changes in the swallowing ability, coughing or choking when eating, shortness of breath during swallowing, food backing up into the mouth or nasal passage, fever or voice changes after swallowing, pain when swallowing, and unexplained weight loss. This study was approved by the Institutional Review Board.

Gastroenterologist-directed FEES (GDFEES) protocol

The GDFEES was performed by an experienced endoscopist (LTH) competent in per-oral upper endoscopy. The endoscopist had 8 years of experience in endoscopy at a tertiary and teaching hospital. He had specialized training in FEES at the Korean Dysphagia Society before this study. The procedure was performed in either inpatients or outpatients in an endoscopic unit or at bedside using a thin video gastroscope (Olympus GIF-XP 260), with an outer diameter of 5 mm. The scope has both up-down and right-left knobs. Before the procedure, the patients and/or caregivers were provided with information about the procedure and adverse events. In addition, a history was obtained, a physical examination of the head and neck was performed, and the heart rate and blood pressure were measured.

To begin the procedure, the patient was placed in an upright sitting position. Generally, the endoscope was inserted via the middle turbinate route; however, endoscopic insertion was performed via the inferior turbinate route if that route was wider. The endoscope was then placed between the end of the soft palate and the epiglottis. The patient was allowed a 1-minute rest period to adapt to the presence of the laryngoscope and prepare for testing. The examination consisted of the Phase I anatomic-physiologic assessment, including velar and laryngopharyngeal anatomy, movement, and sensation; and the Phase II examination of swallowing test diets (Figure 1). For the GDFEES test diets, we first used 5-15 mL of yogurt as a viscous food. This was followed by 5-15 mL of indigocarmine dye mixed with water as a liquid food, one spoon of rice porridge, and one spoon of cooked rice. To minimize the possibility of aspiration during GDFEES, patients with a compromised ability to swallow their own saliva and aspiration during viscous food swallowing were not given liquid or solid foods. The entire clinical procedure was recorded on video, and the videotape analyzed by the endoscopist (LTH). The GDFEES measures included penetration, aspiration, and pharyngeal residue. An 8-point penetration and aspiration scale (12) was documented in all subjects. The pharyngeal residue was defined as retention of the entire given material in the valleculae or pyriform sinuses after the swallow.

Evaluated items

Our patients' medical records were reviewed for demographic data, causes of dysphagia, and the use of aspirin on the GDFEES day. We evaluated the failure of GDFEES, the safety profile (laryngospasm, epistaxis, vasovagal syncope, airway compromise, pre- and post-examination heart rate, pre- and post-examination systolic and diastolic blood pressure, and significant changes in cardiovascular function), and discomfort level. A failure of GDFEES was defined as the incomplete examination of swallowing due to poor cooperation, adverse events, or insertion difficulty. However, an inability to perform liquid or solid food swallowing tests due to severe aspiration of viscous food was not defined as the GDFEES failure. Laryngospasm was defined as true and false vocal cord adduction of more than 2 seconds. Vasovagal syncope was defined as a benign condition characterized by a self-limited fainting episode of systemic hypotension. Airway compromise was defined when patients complained of dyspnea, or their oxygen saturation level was <90%. A significant change in cardiovascular function was defined as either a decrease/increase of 20 mmHg in the blood pressure or a change in the heart rate of 20

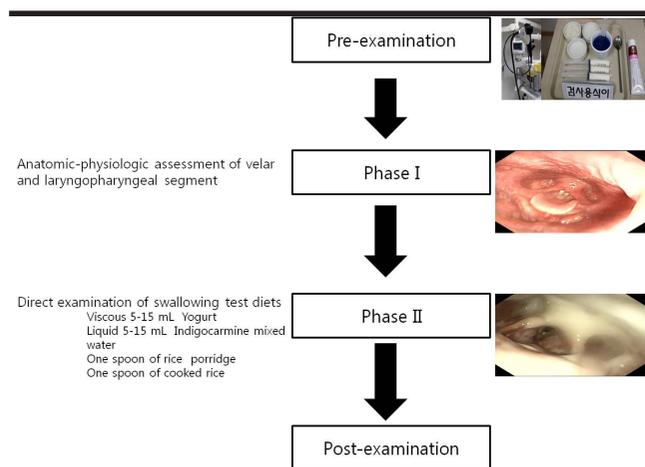


Figure 1. Our protocol of the flexible endoscopic evaluation swallowing study

beats per minute (bpm). A discomfort level during the examination was rated with a visual analog scale based on a scale of 0 to 10; 0 (none), <5 (mild), <8 (moderate), and ≥ 9 (severe). We defined the "moderate" or "severe" discomfort as an indicator of aversion to the procedure. We also considered the level of discomfort as mild when patients would repeat the test if recommended by their physician.

Statistical analysis

Quantitative variables are reported as means and standard deviations, while qualitative variables are reported as proportions. To facilitate statistical analysis of the relationships between age and safety or patient discomfort, patients were grouped by age into the elderly (≥ 65 years) and non-elderly groups (<65 years). To evaluate the effect of experience level on safety/patient discomfort, the calendar period was divided into two periods: December 2011-March 2013 and April 2013-July 2014. The paired t-test was used to assess differences in quantitative variables before and after GDFEES. The χ^2 test was used to evaluate differences in qualitative variables when subgroup analyses were performed. To evaluate the role of aspirin, use on epistaxis during GDFEES, the χ^2 test was also applied. Data were analyzed using the SPSS version 12.0 (SPSS Inc. Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

Table 1. Baseline characteristics of all subjects (n=268)

Gender (%)	
Male	147 (54.9)
Female	121 (45.1)
Age	
Mean age (SD)	67.1 \pm 15.7*
Age ranges	16-100
Causes of dysphagia (%)	
Ischemic stroke	134 (50.0)
Hemorrhagic stroke	69 (25.7)
Malignancy	34 (12.7)
Dementia	11 (4.1)
Traumatic brain injury	2 (0.7)
Parkinson's disease	9 (3.4)
Neuromuscular disease	8 (3.0)
Others [†]	1 (0.4%)
Aspirin use [‡]	69 (25.7%)

*SD, standard deviation; [†] IgG4 disease; [‡] Aspirin use was defined as patients taking aspirin on the day of FEES

RESULTS

The clinical characteristics of all subjects are listed in Table 1. There were 147 males (54.9%) and 121 females (45.1%), with ages ranging from 16 to 100 years (mean age, 67.1 years). The most common cause of dysphagia was ischemic stroke (50%).

Overall subjects

The GDFEES failure occurred in 5 patients (1.7%) due to poor cooperation (n=2) or insertion difficulty (n=3). Poor cooperation was mostly associated with swallowing apraxia, with a marked delay in oral swallowing and no tongue movements when bolus was present. Insertion difficulty was due to an extremely narrow nasal tract associated/unassociated with nasal septal deviations. These patients were excluded from subsequent analyses.

Data describing safety and patient discomfort are summarized in Table 2. There were no instances of laryngospasm, vasovagal syncope, or significant cardiovascular change in any of the examinations. The pre-examination heart rate was 55-99 bpm (mean, 79.8 bpm), while the post-examination heart rate was 55-102 bpm (mean, 80.8 bpm; p<0.001), although no clinical significance was observed. Statistically significant alterations in systolic (+2.4 mmHg) and diastolic blood pressure (+1.4 mmHg) between pre- and post-examinations occurred but were not thought to be clinically significant. There was one episode (0.3%) of decreased oxygen saturation <90% resolved by supportive oxygen therapy. No patients became symptomatically bradycardic or tachycardic. Self-limiting epistaxis occurred in 22 examinations (7.3%) without requiring any type of packing or cauterization therapy. Three (4.3%) of 69 aspirin users had epistaxis, and 19 (8.3%) of non-users had epistaxis, which was not significantly different between aspirin users and non-users. The discomfort ratings were as follows: 128 examinations (43.0%) rated the overall discomfort of the test as none, 150 (50.3%) as mild, 18 (6.0%) as moderate, and 2 (0.7%) as severe discomfort.

Gender subgroup analysis

Epistaxis occurred in 8 (5%) male patients and 14 (10.2%) female patients (Table 3). There was no gender-associated difference in the rate of epistaxis (p=0.084). A significant difference in a discomfort level was not observed between male and female patients (p=0.555), although statistically significant changes in the mean heart rate (+1 bpm) and systolic (+3.1 mmHg) and diastolic (+1.2 mmHg) blood pressure occurred among male patients. However, these differences were not clinically significant. In addition, there

Table 2. Comparisons of FEES failure, safety profiles, and discomfort level

	Current study	Aviv et al. (4)	Cohen et al. (5)	Warnecke et al. (6)	
Setting	Tertiary inpatient/ outpatient gastroenterology practice	Tertiary inpatient/ outpatient otolaryngology setting	Community outpatient otolaryngology setting	Tertiary inpatient acute stroke care unit	
Diameter of endoscopes	5 mm	NA*	4.1 mm	3.1 mm	
Number of patients	268	253	305	300	
Number of examinations	303	500	349	300	
Failure of FEES	5 (1.7%)	2 (0.4%)	0	1 (0.3%)	
Laryngospasm	0	0	0	0	
Epistaxis	22 (7.3%)	3 (0.6%)	4(1.1%)	18(6%)	
Vasovagal syncope	0	0	0	0	
Airway compromise	1 (0.3%)	0	0	0	
Significant cardiovascular change	0	0	0	0	
Pre/post examination mean heart rate	79.8/80.8 [‡]	82/84 [†]	71.9/72.9 [†]	81.5/83.4 [‡]	
Pre/post examination mean SBP	137.3/139.7 [‡]	NA	NA	147.9/151.3 [‡]	
Pre/post examination mean DBP	83.0/84.4 [‡]	NA	NA	74.8/75.9 [†]	
Patient discomfort					
	None	130 (43.6%)	54 (11%)	44 (12.6%)	50(30.3%)
	Mild	149 (50 %)	353 (71%)	169 (48.4%)	88(53.3%)
	Moderate	18 (6%)	77 (15%)	110 (31.5%)	22(13.3%)
	Severe	1 (0.3%)	16 (3%)	26 (7.5%)	5 (3%)

DBP: diastolic blood pressure; SBP: systolic blood pressure

*Flexible laryngoscope; †There was no significant difference between pre- and post-examination; ‡ There was a significant difference between pre- and post-examination

Table 3. Subgroup analyses of epistaxis and discomfort level according to gender, age, and period performed

	Gender			Age*			Period [†]		
	Males n = 161	Females n = 137	p	Non-elderly n = 110	Elderly n = 188	p	First half n = 149	Latter half n = 149	p
Epistaxis	8 (5%)	14 (10.2%)	0.084	8 (7.3%)	14 (7.4%)	0.956	12 (8.1%)	10 (6.7%)	0.658
Patient discomfort			0.555			0.517			<0.001
None	73 (45.3%)	57 (41.6%)		46 (41.8%)	84 (44.7%)		33 (22.1%)	97 (65.1%)	
Mild	80 (49.7%)	69 (50.4%)		55 (50%)	94 (50%)		107 (71.8%)	42 (28.2%)	
Moderate	8 (5%)	10 (7.3%)		8 (7.3%)	10 (5.3%)		8 (5.4%)	10 (6.7%)	
Severe	0	1 (0.7%)		1 (0.9%)	0		1 (0.7%)	0	

*To facilitate statistical analysis of the relationships between age and safety/patient discomfort, all patients were divided according to age into the elderly (≥65 years) and non-elderly groups (<65 years); †To evaluate the effect of experience level on safety/patient discomfort, the study period was divided into two periods: first half (Dec 2011-Mar 2013) and latter half (Apr 2013-Jul 2014)

were statistically significant alterations in the mean heart rate (+0.9 bpm), systolic (+1.7 mmHg), and diastolic (1.6 mmHg) blood pressure among female patients.

Age subgroup analysis

Epistaxis occurred in 8 (7.3%) non-elderly patients and 14 (7.4%) elderly patients (Table 3). There was no significant

difference in the rate of epistaxis ($p=0.956$) between the two subgroups. A significant difference in a discomfort level was not observed between non-elderly and elderly patients ($p=0.517$). Statistically significant changes in the mean heart rate (+1.1 bpm) and systolic (+2.3 mmHg) and diastolic (+1.2 mmHg) blood pressure occurred in non-elderly patients. However, these differences were not clinically significant. Among elderly patients, there were only statistically significant alterations in the mean heart rate (+1.4 bpm) and systolic (+2.5 mmHg) and diastolic (1.5 mmHg) blood pressure.

Experience level subgroup analysis

Epistaxis occurred in 12 (8.1%) patients in the first period and 10 (6.7%) in the latter period (Table 3). There was no significant difference in the rate of epistaxis ($p=0.658$) between the two subgroups. In the first period, the patient discomfort was noted as follows: none (22.1%), mild (71.8%), moderate (5.4%), and severe (0.7%). In the latter period, patients rated discomfort as none (65.1%), mild (28.2%), moderate (6.7%), or severe (0%). A significant difference in a discomfort level was observed between non-elderly and elderly patients ($p<0.001$). Statistically significant changes in the mean heart rate (+2.1 bpm) and systolic (+2.3 mmHg) and diastolic (+1.4 mmHg) blood pressure occurred in non-elderly patients. However, these differences were not clinically significant. There were only statistically significant alterations in the mean heart rate (+1 bpm) and systolic (+2.8 mmHg) and diastolic (+1.5 mmHg) blood pressure among elderly patients.

DISCUSSION

In our study, we describe the GDFEES as a well-tolerated and safe method for evaluating OPD. The procedure was performed in a gastroenterology setting by an experienced endoscopist without any involvement of SLPs. In South Korea, with a limited availability of specialized SLPs, the introduction of FEES examination into endoscopy suites might prepare many gastroenterologists to provide relevant OPD practice in their dysphagic care, resulting in a more appropriate management and referral for patients with OPD.

In our study, the rate of failure to complete a FEES examination was similar to those of previous studies from the otorhinolaryngology setting. A large unседated TNE study demonstrated that the causes of failure were unsuccessful transnasal insertion (62.7%), patient refusal (19.4%), and nasal pain (17.9%) (13). Our main concerns regarding a successful GDFEES were a narrow nasal pas-

sage and buccofacial apraxia. Insertion difficulty might be sometimes overcome by using a thinner diameter of the endoscope. However, the administration of food failed in some patients because patients with buccofacial apraxia were unable to open their mouths adequately or to transport any bolus by coordinated tongue propulsion into their hypopharynx. Therefore, it is critical to screen these patients with swallow apraxia before the GDFEES. The brain lesion is typically in or near the area 44 (the Broca's area) in patients with buccofacial apraxia (14). They are unable to perform tasks with their mouth, such as blowing out a match, kissing, or brushing their teeth. Appropriate review of previous imaging tests and simple tests for buccofacial movement could be helpful to reduce unnecessary GDFEES.

Patient discomfort was actually the most common adverse event of GDFEES. In this study, >90% of patients rated FEES as causing no or mild discomfort. Only 6.7% would not repeat the test despite their physician's recommendation to do so. Our data regarding discomfort were consistent with previous studies (4-6). Although we used an endoscope with a larger diameter, the reasons for achieving comfort during FEES included the endoscopist's high level of expertise and careful performance of the procedure through the nasal passage, since maximal discomfort primarily occurred during passage through the nasal cavity. It is also important to select a wider route of endoscopic insertion (the inferior turbinate vs. the middle turbinate).

Several SLPs or otolaryngologists-performed studies reported that older patients tolerate endoscopic procedures better than younger patients do (13, 15-19). These results could be associated with differences in mucosal sensation. In addition, it has been reported that females have poor tolerance to endoscopic procedures compared with males (13,20,21). In this study, a discomfort level greater than mild severity during the first half was 77.9%, dropping to the discomfort level of 34.9% in the latter period. This result may be related to the fact that the accumulated experience would decrease patient discomfort. The excessive gag response may also be the cause of discomfort during GDFEES. Therefore, the endoscope should be positioned in the center to avoid contact with the lateral pharyngeal wall or the base of the tongue. It is noted that sudden movements of the endoscopic shaft induce pressure on the intranasal surfaces, causing uncomfortable GDFEES. The endoscope was covered with a water-soluble lubricant before insertion. This lubricant helps to decrease pain during passage of the endoscope

through the nasal cavity. The use of topical anesthesia with/without a vasoconstrictor during the procedure has been debated ever since the FEES procedure. Topical anesthesia is associated with allergies and/or sensitivities, as well as the potential for affecting swallowing. However, recent studies reported that topical anesthesia improved the patient comfort and tolerance of the procedure without affecting the swallowing function clinically (22–24). The appropriate use of topical anesthesia may help to decrease examination discomfort, although topical anesthesia was not used in our study. Educating the patient and/or caregiver regarding the GDFEES rationale is necessary for enhancing comfort during the examination. It is noted that differences in either individual sensitivity or cultural expectations affect the discomfort level.

Our study showed a higher incidence of self-limiting epistaxis compared with previous studies. This is associated with the use of an endoscope larger in diameter. Some patients tend to move their head during the endoscopic passage through the nasal cavity and thereby cause trauma to the nasal mucosa. The larger endoscope appears to have a higher potential of causing this trauma, especially in less cooperative patients.

Our study and previous studies reported no incidents of laryngospasm and vasovagal syncope. However, the survey showed two incidences of laryngospasm and four vasovagal syncope episodes among the 6000 FEES examinations performed by 64 SLPs and 9 physicians (25). Although the likelihood of FEES provoking laryngospasm or vasovagal syncope is extremely low, FEES examiners should be careful with these complications, since laryngospasm can be elicited intentionally when the examiner touches the false vocal cord to test sensation.

There were some limitations in this present study. This is a retrospective study, which relies on the accuracy of written record analysis and is difficult to control confounders such as no blinding. We enhanced the accuracy and completeness of the retrospective data by prospectively collecting structured reports in GDFEES examination. This examination was performed by an experienced endoscopist in a tertiary medical hospital. Therefore, the results might not be generalized to other average gastroenterology practice settings. A learning curve study involving an unsedated transnasal endoscope application indicated trainee achieved the technical competency even within the first 10 procedures (26). From the endoscopist's perspective, the technical feasibility would not be major limitations of GDFEES examination. However, this

examination requires the comprehensive understanding of swallowing pathophysiology and interpretation skills of FEES results (27).

Currently, FEES is the most commonly used method for the objective assessment of swallowing (28). When deciding who should perform FEES, it is a contested issue. The best answer is, whoever learns systematically FEES the best. There are two FEES accreditation programs providing a thorough education for using FEES to evaluate the oropharyngeal swallowing in neurological and geriatric patients and to establish a formal diagnosis of OPD (29, 30). These programs are open to allied health care professionals. According to the European Society for Swallowing Disorders, qualifications required for the FEES certificate include (1) the proof of training in an institution with FEES expertise; (2) 2 years of experience in the area of FEES with patients presenting with OPD; (3) a minimum of 200 performed evaluations; and (4) passing a written onsite exam provided by the accreditation board (30).

In conclusion, this first study indicates that the GDFEES is safe and tolerable procedure in patients with OPD. This research can be endorsed as an appropriate paradigm for clinical practice based on our study investigating its safety and tolerance. However, further research is needed to confirm the result in other gastrointestinal endoscopic practice settings. More importantly, it is less important who should perform FEES but that a qualified FEES is done at all. Therefore, gastroenterologists should have a thorough education for using FEES before performing the GDFEES.

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Review Board of Soonchunhyang University Seoul Hospital (Decision Date: March 16, 2018; Decision No.: SCHIRB-2018-03-005).

Informed Consent: Informed consent is not necessarily due to the retrospective nature of this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - T.H.L.; Design - T.H.L.; Supervision - J.S.L.; Data Collection and/or Processing - T.H.L.; Writing Manuscript - T.H.L.; Critical Review - J.S.L.

Conflict of Interest: The authors have no conflict of interest to declare.

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