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Flexible endoscopic incisional therapy for Zenker's diverticulum (FEIT-Z) is an effective treatment for surgical failures or non-operative patients

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Abstract

Background Symptomatic Zenker's diverticulum (ZD) occurs mostly in the elderly, who often have significant comorbidities, and poor neck hyperextension, putting them at high risk for surgical management while also increasing the potential of technical failure. Flexible endoscopic incisional therapy for Zenker's diverticulum (FEIT-Z) offers a safe approach to this problem with high technical and clinical success rates. There are limited data on its use following a failed surgical approach or in patients unfit for a surgical approach. The aim of this study was to assess clinical and technical outcomes of FEIT-Z in patients who were non-operative candidates or refused or failed surgical management.

Methods Patients who underwent FEIT-Z from January 2015 to February 2019 at a tertiary referral center were included. Patient demographics, prior ZD surgical history, procedural data, dysphagia scores, clinical success, and adverse events (AE) were collected. Univariable analysis was performed to assess differences between pre- and post-FEIT-Z dysphagia scores.

Results 30 patients undergoing FEIT-Z were included. Seven had a prior failed ZD surgical approach, 6 refused surgical management, and 17 were deemed to be non-operative candidates based on medical comorbidities. Mean age was 78.4 (± 12.1) and 36.7% were male. Technical success of FEIT-Z was 96.7%. There was a significant improvement in dysphagia scores after FEIT-Z: 2.3 (± 0.64) vs. before, 0.4 (± 0.76) ($p < 0.001$). Long-term clinical success was achieved in 73.3% of patients. Adverse events were seen in 23.3% of patients; however, these were graded as mild in 85.7% of patients. One microperforation was managed with antibiotics.

Conclusion FEIT-Z is a safe procedure with low adverse events and a high rate of technical and clinical success. FEIT-Z can be done in patients who fail previous surgical treatment, refuse a surgical approach, or are not surgical candidates due to medical comorbidity or other factors.

Keywords Endoscopy · Zenker's diverticulum · Cricomyotomy · Weerda diverticuloscope · Dysphagia

Zenker's diverticulum (ZD) is an acquired false diverticulum formed by outpouching of the mucosa and submucosa through Killian's triangle, formed by the oblique fibers of the inferior pharyngeal constrictor muscle and the cricopharyngeal sphincter [1, 2]. ZD typically presents in patients over 70, and symptoms can go on for months or years before diagnosis [3]. Common symptoms include dysphagia, halitosis, regurgitation, and aspiration.

Current treatment options for ZD include transcervical cricomyotomy with or without diverticulectomy, speculum-assisted rigid endoscopic cricomyotomy, or flexible endoscopic cricomyotomy. These procedures have the aim of removal of the functional outflow obstruction by myotomy of the cricopharyngeal bar [4]. There are no randomized, prospective, controlled trials comparing the various methods of treatment and consequently, management is often determined by referral patterns and local expertise [2, 5].

Because ZD patients tend to be older, they often have significant comorbidities, making a surgical approach riskier. In addition, higher rates of cervical spine disease in the elderly may interfere with the amount of neck hyperextension required for some surgical approaches [6]. Also, with the speculum-assisted surgical approach, smaller diverticula

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may have inferior operative outcomes due to limitations of current staplers and cutters.

Flexible endoscopic incisional therapy for ZD (FEIT-Z) has emerged as a cost effective and safe modality of treatment of symptomatic diverticula [7, 8]. FEIT-Z is performed using a flexible gastroscope usually fitted with a clear distal attachment to improve visualization. A needle-knife type of cautery instrument is used to perform the cricopharyngeal myotomy. There is a long track record of safety and efficacy of FEIT-Z [9].

In this study, we report clinical and technical outcomes for FEIT-Z in patients who refused or failed initial surgical management or were deemed non-operative candidates due to medical comorbidity.

Materials and methods

Patients

This is a historical case series of a prospective database in which 47 patients undergoing FEIT-Z between January 2015 and January 2019 were eligible for inclusion. The study was approved by the Geisinger Medical Center IRB. Most patients included in the study had undergone a surgical evaluation for surgical treatment of ZD by a head and neck surgeon and either refused surgical management or were deemed a non-operative candidate secondary to comorbidities. Other patients were included in the study if they had previously undergone a surgical intervention for ZD (transcervical cricomyotomy or speculum-assisted rigid endoscopic cricomyotomy) and had recurrent symptomatic dysphagia. Patients were excluded if they did not undergo previous surgical evaluation, surgical treatment of ZD, or were lost to follow-up following FEIT-Z.

Study definitions

All patients had dysphagia which was evaluated before and after endoscopic treatment using a standard symptom score from 0 to 4 (0, normal swallowing; 1, dysphagia for solids alone; 2, dysphagia to soft solids; 3, dysphagia to solids and liquids; 4, inability to swallow saliva) [10].

Patients were followed up in the clinic or with a telephone interview following FEIT-Z at 1 month and thereafter at 6-month intervals. Patients were encouraged to call the clinic sooner if they experienced ongoing or recurrent symptoms. A large ZD was defined as >2 cm and a small ZD as ≤ 2 cm. All patients had a preprocedural esophagram. Esophagram was only obtained postprocedurally if there was a concern for adverse event at the discretion of the endoscopist or if there were ongoing or recurrent symptoms following FEIT-Z.

Technical success was defined as the ability to complete all aspects of the FEIT-Z procedure from beginning to end. Short-term clinical success was defined as resolution of dysphagia (symptom score of 0) at 6 months following FEIT-Z. Any persistent dysphagia was classified as a clinical failure of FEIT-Z. Long-term success was defined as resolution of dysphagia (symptom score of 0) that persisted >6 months and the patient remained dysphagia free at the end of the study period.

Adverse events were defined as an event associated with a technical aspect of the procedure that prevented completion of the planned procedure and/or resulted in admission to hospital, prolongation of existing hospital stay, another procedure, or a subsequent medical consultation. Adverse events were graded based on the ASGE lexicon as mild, moderate, and severe [11].

FEIT-Z procedure

All FEIT-Z procedures were done with endotracheal intubation and endoscopic CO_2 insufflation by two endoscopists with extensive experience performing FEIT-ZA clear distal cap attachment was affixed to a diagnostic gastroscope (GIF-180 or GIF-190, Olympus, Center Valley, PA). The length of the diverticulum was measured and if debris was present within the diverticulum, it was cleared.

Cricopharyngeal myotomy was usually performed with an IT-2 Knife (KD-611L, Olympus, Center Valley, PA), earlier in the series the Hook Knife was used (KD-620LR, Olympus), and more recently the SB knife, standard type has been utilized (MD-47706, Sumitomo Bakelite Co., Ltd, Tokyo, Japan).

Briefly, the flexible incisional treatment is done by cutting the mucosa at the cricopharyngeal bar between the esophageal lumen and diverticular lumen. This can be done with one of the ESD knives or the SB knife, which is a scissor-type cutting device. After the mucosa is cut, the underlying cricopharyngeus muscle can be seen and then cut. The cutting is taken down near to the base of the diverticulum. At this point, sectioning of the cricopharyngeus muscle is stopped. At the endoscopist's discretion, one or two endoscopic clips were placed after cricopharyngeal myotomy at the midpoint of the incision. Routine periprocedural antibiotics were given in only a few procedures at the discretion of the endoscopist.

Patients were discharged the same day after the endoscopy after standard post-procedure recovery of about one hour. Patients could take liquids orally on the same day of the FEIT-Z procedure. They were advised to pursue a soft diet for 3 days and then advance their diet as tolerated.

Statistical analysis

Descriptive statistics were computed for all variables. These included means, standard deviations, and percentiles for continuous factors and frequencies for categorical variables. A univariable analysis was performed to assess differences in dysphagia scores between patients pre- and post-FEIT-Z. Student's *t* tests and Wilcoxon rank sum tests were used for continuous variables and Pearson's chi-square or Fisher's exact tests were used for categorical variables. A $p < 0.05$ was considered significant. SAS version 9.2 software (The SAS Institute, Cary, NC) was used for all analyses.

Results

Of the 47 patients evaluated for the study, 11 were excluded because they did not undergo surgical evaluation or surgical treatment of ZD prior to performing FEIT-Z. An additional 6 patients were excluded because they had incomplete follow-up data. Of these 6 patients, 3 died prior to the 6 months follow-up period secondary to their underlying comorbidities and not related to FEIT-Z and 3 were completely lost to follow-up. A total of 30 patients met all criteria and were included in the study (Fig. 1).

Seven patients (23.3%) failed prior surgical treatment. Five of these patients failed rigid endoscopy, one patient failed open surgical approach, and one patient failed both rigid and open approaches. Seventeen patients (56.6%) were deemed as non-operative candidates. The most common comorbidities precluding surgical management were cardiac disease, vascular disease, including stroke, pulmonary disease, and dementia. One patient had stage IV pancreatic cancer. Three patients evaluated by a head and neck surgeon were felt not to be amenable to surgical approach due to small size of the diverticulum and were referred for FEIT-Z. Six patients (20%) were evaluated by a surgeon but declined surgical management (Table 1).

The mean age of patients undergoing FEIT-Z was 78.4 (± 12.1) years and 36.7% of patients were men. All patients included in the study were Caucasian. The mean procedure time was 33.5 (± 15.6) minutes. Seventy percent of the cohort had a large ZD. One or more prophylactic clips was placed in 20% of patients and a single dose of periprocedural antibiotics was given in 10% of procedures. The IT-2 knife was most used (46.7%) followed by a combination of endoscopic knifes (30%), Hook Knife alone (13.3%), and the SB knife (10%).

Technical success was achieved in 29 patients (96.7%). The only technical failure was secondary to incomplete myotomy in one patient with a small ZD. The average pre-FEIT-Z dysphagia score of 2.3 (± 0.64) was significantly worse compared to the mean post-FEIT-Z dysphagia score

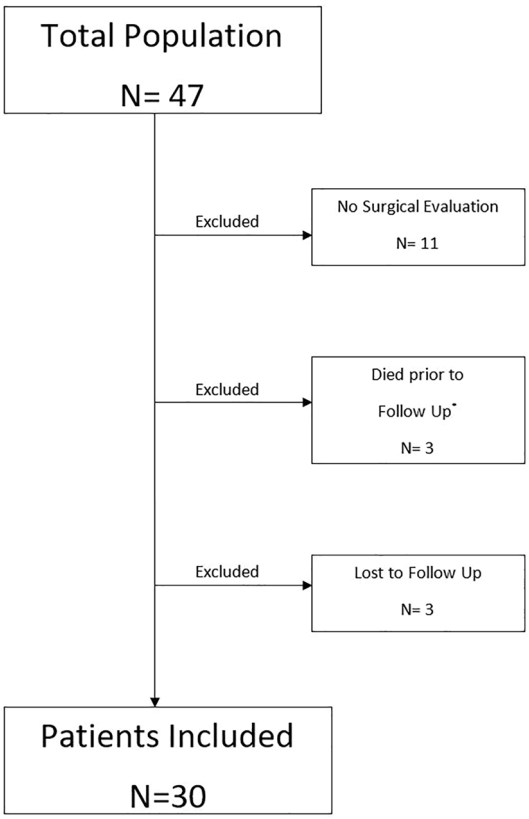

Fig. 1 Flow sheet of patients included in the study. (*Death was from advanced cancer and not attributable to FEIT-Z)

of 0.4 (± 0.76) ($p < 0.001$). Short-term clinical success (resolution of dysphagia (symptom score of 0) at 6 months) was achieved in 20 patients (66.7%). Four of the 10 short-term clinical failures underwent at least one additional FEIT-Z procedure with 50% of those obtaining long-term clinical success. Long-term clinical success (resolution of dysphagia (symptom score of 0) that persisted > 6 months) was achieved in 73.3% of patients (Table 2).

When stratified by sex, 81.8% of males had long-term relief of dysphagia compared to 68.4% of females (odds ratio (OR) 2.08 (95% CI 0.34, 12.7), $p = 0.67$). Similarly, those that had a large diverticulum had a 3.4 (95% CI 0.62, 18.75) higher chance of long-term resolution of dysphagia; however, this did not achieve statistical significance ($p = 0.19$). Finally, there was no difference between patients who refused or were not surgical candidates in terms of long-term resolution of dysphagia: OR 1.13 (95% CI 0.17, 7.47), $p = 0.72$).

Seven patients had an adverse event (23.3%). Based on the ASGE lexicon 85.7% of the adverse events were graded as mild, 14.3% as moderate, and none as severe. The most common mild adverse event was mild throat pain which was experienced by six patients. One patient (3%) had a perforation which was managed with short hospitalization, nil per

Table 1 Baseline demographics stratified by failure of prior Zenker's diverticulum surgical approach or declined/deemed high risk for a surgical approach

Factor	Failed prior ZD surgery ($N=7$) Mean ± SD or number (%)	Declined or deemed high risk for surgery ($N=23$) Mean ± SD or number (%)	p value
Male	3 (42.9)	8 (26.7)	0.99
Age	76.6 ± 12.6	79.0 ± 12.4	0.65
Gender			1.0F
Caucasian	7 (100)	23 (100)	
Baseline large diverticulum	2 (28.6)	19 (82.6)	**0.01**
Pre FEIT-Z dysphagia score	2.22 ± 0.67	2.57 ± 0.53	0.21
Post FEIT-Z dysphagia score	0.28 ± 0.49	0.44 ± 0.84	0.66

Bolded p values indicate statistical significance

Table 2 Factors associated with long-term (LT) clinical success in patients undergoing flexible endoscopic therapy for Zenker's diverticulum (FEIT-Z)

Factor	LT clinical success ($N=22$) Mean ± SD or number (%)	LT clinical failure ($N=8$) Mean ± SD or number (%)	p value
Male	9 (40.9)	2 (25.0)	0.44
Age	81.8 ± 9.2	69.1 ± 13.9	**0.01**
Pre-FEIT-Z dysphagia score	2.1 ± 0.6	2.8 ± 0.4	**0.02**
Post-FEIT-Z dysphagia score	0.0 ± 0.0	1.5 ± 0.7	**< 0.001**
Technical success	22 (100)	7 (87.5)	0.27
Device used for FEIT-Z			0.21
Insulated Tip (IT-2)	11 (50.0)	3 (37.5)	
Hook knife	4 (18.2)	0 (0.0)	
SB knife	2 (9.1)	1 (12.5)	
> 1 knife used	5 (22.7)	4 (50.0)	
Failed prior surgery	5 (22.7)	2 (25.0)	0.90
Baseline large diverticulum	17 (77.2)	4 (50.0)	0.19
Prophylactic clip used	5 (22.7)	1 (12.5)	0.99
Any adverse event	6 (27.2)	1 (12.5)	0.64

Bolded p values indicate statistical significance

os, and intravenous antibiotics. The patient did not require any operative or non-operative intervention.

Discussion

FEIT-Z is an effective and safe procedure for symptomatic ZD in patients who have failed or refused prior surgical intervention or are poor surgical candidates. In this selected population of hard to manage patients, a 97% technical success rate and 73.3% long-term clinical success rate were achieved with FEIT-Z. The availability of flexible endoscopic management of ZD increases the range of patients that can be successfully managed.

Current transoral approaches to ZD management typically utilize a speculum to expose the cricopharyngeal bar, followed by cutting and stapling with rigid staplers or with rigid cautery devices, such as a harmonic scalpel. These approaches require the patient to be able to hyperextend the neck and to have wide enough jaw opening. In this series, there were 6 patients unable to successfully undergo rigid endoscopic treatment due to limitations related to inability to insert the speculum. In addition, the ZD must be long enough to accommodate the active end of the cutting device. The staple load is not at the tip of the stapler and thus inadequate extent of stapling can be encountered, particularly in smaller diverticula. Three patients (10%) in our cohort had ZD felt by a surgeon to be "too small" for rigid endoscopic management.

The flexible endoscopic approach can overcome these limitations. A 10- or 11-mm standard flexible video endoscope with a distal clear cap attachment is used, and neck hyperextension is not necessary. Division of the cricopharyngeus is usually accomplished with a needle-knife type of monopolar cautery device, which is small enough to be placed precisely. Adverse effects of FEIT-Z such as bleeding or perforation are uncommon. "Microperforation" resulting in minor extravasation of carbon dioxide into the soft tissue around the cricopharyngeus may occur but can typically be managed without specific intervention. The surgical approaches for ZD have other complications not seen with FEIT-Z, for example, laryngeal nerve injury with resulting vocal cord paralysis. All outpatients who underwent FEIT-Z in this series were discharged home on the same day of the procedure. Surgical ZD patients typically are admitted for observation after the procedure, with a mean length of stay between 2 and 3.5 days [12, 13]. Another advantage of

FEIT-Z is the ability to resume oral nutrition within 24 h after the procedure, whereas surgical patients may be typically maintained on parenteral nutrition or nasogastric feeds postoperatively [9].

Technical challenges that may be encountered during transoral rigid endoscopic treatment of ZD can result in surgical failures or conversion to open surgical management [14]. Our study serves to highlight that in these cases FEIT-Z can offer a "rescue" treatment. With available expertise, a difficult surgical case can be switched to the flexible endoscopic approach "on the fly" so that completion of the procedure can be accomplished, saving the patient a second anesthesia session.

In this series, the one technical failure was also a clinical failure in a patient who had failed prior surgical intervention for ZD. She was a 60-year-old female with dysphagia following implantation of cervical orthopedic hardware after cervical spine surgical intervention. The technical failure of FEIT-Z was because of extreme tightness at the neck of the Zenker's diverticulum precluding the scope from entering the diverticulum completely. This prevented complete myotomy with the IT-2 knife. In retrospect, this patient likely had a traction pharyngeal diverticulum related to a previous cervical spine operation, which may be better treated by explantation of cervical hardware than by cricomyotomy [15].

Short-term clinical resolution was achieved in 66.7% of the ZD patients after one session of FEIT-Z. A second session of FEIT-Z in one patient and in one case a third session led to a sustained clinical response, resulting in an overall long-term success rate of 73.3%. The recurrence rate of dysphagia after FEIT-Z described in published studies ranges from 11 to 35% [16–18]. One study attributed recurrence to larger size of the diverticulum [18]. Due to the heterogeneity of these studies, the factors contributing to recurrence after FEIT-Z is difficult to determine. Different lengths of follow-up, use of different devices, and varying sample sizes between published studies contribute to this variation. Our AE rate of 23.3% compares favorably to the 11.3% AE rate in Ishaq et al.'s systematic review and meta-analysis of FEIT-Z especially considering that 85.7% of AE were mild (All had self-limited throat pain), 14.3% moderate, and none as severe [9].

Success rates with FEIT-Z have been noted to be similar in comparison to rigid endoscopy and open surgical management. Antonello et al. [19] reported 84% clinical success in patients receiving FEIT-Z with prior history of surgical management or rigid endoscopy for ZD, followed by 100% symptom resolution after second FEIT-Z in patients with relapse. This is comparable to our clinical success rate of 73.3%, respectively. In addition to comparable success rates, FEIT-Z has significantly lower morbidity rate in comparison to surgical interventions for ZD, which can be as high as 30% [20]. The advantages of fewer complications, lower morbidity and mortality, and favorable outcomes in non-operative candidates and patients with prior failed treatment may make FEIT-Z a preferred treatment option for selected patients.

There are some important limitations of this study to point out. First, all procedures were done at a single tertiary medical center by very experienced interventional endoscopists with a high degree of expertise in the FEIT-Z procedure. Results of the procedure when done by endoscopists earlier on their learning curve would likely be worse. In addition, the sample size of 30 patients is somewhat limited; however, this does represent results from "real world" clinical indications for the procedure in an institution where both open surgical, rigid endoscopic, and flexible endoscopic approaches are all done.

FEIT-Z is a useful technique for managing ZD in patients that failed prior surgical intervention, are deemed poor surgical candidates, or who refuse surgical management. FEIT-Z has a low rate of AEs, and a high technical and clinical success. Elderly patients with multiple significant comorbidities who are poor surgical candidates can be managed safely and effectively with FEIT-Z. In cases of failed surgical management by other means, FEIT-Z is a useful salvage therapy.

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Declarations

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