

Title:

Prospective case series of non-tunnel, non-injection Z-POEM (NiZ-POEM) for Zenker's diverticulum – Safety and short-term outcomes

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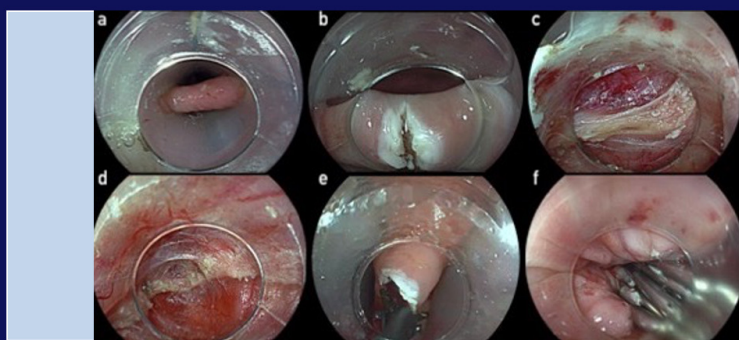
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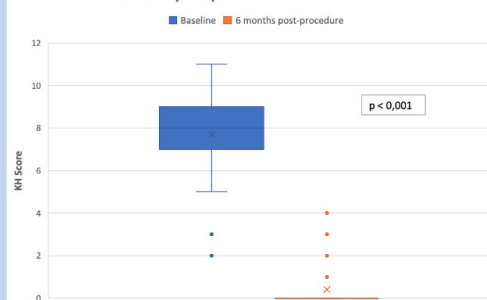
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Safety and short-term outcomes of Non-Tunnel Non-Injection technique (NiZ-POEM) for the treatment of Zenker's Diverticulum (ZD): a case series.



Baseline and post-procedure Kothari-Haber Score



Single-center prospective study (N=24)
Mean diverticulum size 25 mm (± 11.5)
Median procedure time 36.5 (range 22-91)

Technical success 100%
Clinical success 100%
Adverse events 0%

NiZ-POEM is a safe and effective technique for the treatment of Zenker's diverticulum.

Accepted

Prospective case series of non-tunnel, non-injection Z-POEM (NiZ-POEM) for Zenker's diverticulum – Safety and short-term outcomes

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Autorship declaratioin according to CRediT standards:

Miguel Fraile-López: endoscopist operator, data recording and paper edition.

Carmen Ribes Peiró: data recording, patient recruitment and paper edition.

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Abbreviations list:

ZD: Zenker's diverticulum

FES: flexible endoscopic septotomy

Z-POEM: peroral endoscopic myotomy for Zenker's diverticulum

NiZ-POEM: non-injection non-tunnel technique for peroral endoscopic myotomy of Zenker's diverticulum.

KHSS: Kothari-Haber Scoring System

ESD: endoscopic submucosal dissection

AE: adverse events

ASGE: American Society of Gastrointestinal Endoscopy

CI: Confidence Intervals.

ASA: American Society of Anesthesiologists.

CCI: Charlson Comorbidity Index

MDADI: MD Anderson Dysphagia Inventory

SD: standard deviation

CUSUM: cumulative Sum Control Chart.

Conflict of interest:

Miguel Fraile-López: Olympus (Educational activities), CreoMedical (Research grant), Fujifilm (Research grant).

Lay summary:

Flexible endoscopic procedures have been established as the standard therapeutic approach for Zenker's diverticulum. Recently, Z-POEM technique has emerged as an advanced tailored alternative. However, it requires high level of endoscopic expertise. To address this limitation, the NiZ-POEM recently described avoids the need for submucosal injection and tunneling, substantially reducing procedural time. In addition, we suggest the use of a diverticuloscope to decrease the technical demands

of Z-POEM and enhance its applicability.

The aim of this study was to evaluate the safety and effectiveness of NiZ-POEM after at least 6 months of follow-up. Technical and clinical success was achieved in all cases, with no adverse events or symptom recurrence. There was a significant improvement in dysphagia, with a Dakkak-Bennett <1 in all cases and a median baseline Kothari-Haber Score System decreasing from 8 (2-11) to 0 (0-4) at 6 months post-procedure ($p<0.001$). Quality of life improved significantly, with MDADI scores increasing from 53 (26-90) at baseline to 95 (71-100) at 1 month (median 41, IQR 32-49) (2.5; 95% CI 2.08-2.92) and 99 (65-100) at 6 months (median 41, IQR 36-48) (2.54; 95% CI 2.12-2.96). Furthermore, the median procedure time was 36.5 minutes (22-91), notably shorter than previously reported in the literature.

NiZ-POEM is a safe and effective technique for the treatment of Zenker's diverticulum. Its simplified approach may broaden the applicability of Z-POEM in clinical practice.

Key points:

NiZ-POEM, a novel modification of the Z-POEM technique, eliminates the need for submucosal injection and tunneling, potentially reducing procedure time.

The diverticuloscope use simplifies the procedure and could increase its applicability by lowering technical skill requirements.

This study demonstrates the safety and effectiveness of NiZ-POEM, with no adverse events or symptom recurrence reported after six months of follow-up.

AI usage statement (if applicable):

Not used

Abstract

Background: Zenker per-oral endoscopic myotomy (Z-POEM) is increasingly used for the treatment of Zenker's diverticulum. This study aimed to evaluate the safety and short-term outcomes of the novel non-tunnel non-injection Z-POEM (NiZ-POEM) technique for Zenker's diverticulum.

Methods: This single-center prospective study included patients with symptomatic Zenker's diverticulum who underwent NiZ-POEM between February 2023 and February 2025. The primary outcomes were technical and clinical success at 6 months. Secondary outcomes included quality-of-life improvement, adverse events rates, symptom recurrence and reintervention rates.

Results: A total of 24 patients were included, with a median age of 77.5 years (54-98); 16 patients (66.7%) were male. Four patients (16.7%) had previously undergone treatment with subsequent symptom recurrence. The mean diverticulum size was 25 mm (± 11.5) and the median procedure time was 36.5 minutes (22-91). Technical success was achieved in all patients, and clinical success at 6 months was 100% (95% CI 86.2-100%). There was a significant improvement in dysphagia, with Dakkak-Bennett <1 in all cases and median baseline Kothari-Haber Score System decreasing from 8 (2-11) to 0 (0-4) at 6 months post-procedure ($p < 0.001$). Quality of life improved significantly, with MDADI scores increasing from 53 (26-90) at baseline to 95 (71-100) at 1 month (median 41, IQR 32-49) and 99 (65-100) at 6 months (median 41, IQR 36-48). No adverse events occurred, and no symptom recurrence was observed during follow-up.

Conclusion: NiZ-POEM is a safe and effective technique for the treatment of Zenker's diverticulum. Its simplified approach may broaden the applicability of Z-POEM in clinical practice.

Keywords: Zenker's diverticulum. Peroral endoscopic myotomy. Third-space endoscopy.

INTRODUCTION

Zenker's diverticulum (ZD) is a protrusion of the pharyngeal mucosa through a defect in the posterior pharyngeal wall, typically located at Killian's triangle, a virtual space between the inferior constrictor and the cricopharyngeal muscles (1). The prevalence of ZD in the general population is estimated to range from 0.01% to 0.11% (2). Associated symptoms -including dysphagia, oropharyngeal regurgitation, chronic cough, and aspiration pneumonia- can significantly impair quality of life.

Flexible endoscopic septotomy (FES) has demonstrated improved outcomes compared with traditional diverticulectomy and rigid endoscopy (3,4). However, both incomplete and excessive cutting of the cricopharyngeal septum may result in symptom recurrence or serious complications, including perforation and mediastinitis (4). To mitigate these risks, third-space endoscopic techniques have been developed, offering more tailored treatments but requiring advanced technical expertise.

Since the initial description of Zenker's peroral endoscopic myotomy (Z-POEM), several modifications have been proposed with the aim of reducing technical complexity, improving clinical outcomes, and minimizing complications (5,6). More recently, the non-injection non-tunnel technique (NiZ-POEM) has emerged as a simplified alternative to conventional Z-POEM (7). This technique involves a mucosal incision followed by direct cricopharyngeal myotomy, thereby eliminating the need for prior injection and tunneling. By streamlining the procedure, NiZ-POEM may enhance feasibility, shorten procedure times, and potentially improve outcomes.

The aim of this study was to evaluate the safety and short-term clinical outcomes of NiZ-POEM in the treatment of ZD.

MATERIAL AND METHODS

Study design

This is a prospective cohort of patients diagnosed with and treated for symptomatic ZD using NiZ-POEM at a tertiary center between February 2023 and February 2025. Symptomatic individuals previously diagnosed with ZD who had previously declined treatment because comorbidities and potentially procedure-related adverse events (AE) and those who experienced symptom recurrence after prior treatment were re-invited for consultation and offered NiZ-POEM as an alternative.

The study was approved by the local ethics committee (code: 2024.367), and informed consent was obtained from all participants. The study was conducted in accordance with the STROBE guidelines (8).

Patients and Z-POEM procedure

ZD was diagnosed by gastroscopy and barium esophagogram. In cases of symptom recurrence, both diagnostic modalities were repeated to determine the need for further intervention. All procedures were performed under general anesthesia with the patient in the left lateral position. A single prophylactic antibiotic dose was administered pre-procedure. A diverticuloscope was used whenever feasible. For small diverticula in which adequate septal isolation was not possible, the decision to proceed without it was left to the endoscopist's discretion. High-definition diagnostic or therapeutic gastroscopes with auxiliary water channels were used (EG-760R Fujifilm, Tokyo, Japan). A transparent conical cap was attached to the scope tip, and CO₂ insufflation was maintained throughout the procedure. Two scissor-type knives were employed: Clutch Cutter (DP2618DT, Fujifilm Medical, Tokyo, Japan) and SB Junior knife (Sumitomo Bakelite Co., Ltd., Tokyo, Japan). Electrosurgical settings included Endo Cut Q (effect 1, duration 2, interval 1) and soft coagulation (80W, effect 4). When bipolar forceps (Hemostat-Y, Pentax Medical, Spain) were used, soft coag was applied (90W, effect 5) (ERBE, Tübingen, Germany). Myotomy and mucosotomy lengths were tailored in each patient using the "double sticker over knife technique" previously described by our group (9).

Z-POEM procedural steps (Figure 1):

1. Placement of a guidewire into the stomach.
2. Insertion of the diverticuloscope over the guidewire.

3. Mucosal incision with a scissor-type knife.
4. Direct cricopharyngeal myotomy and mucosotomy under direct visualization.
5. Withdrawal of the diverticuloscope.
6. Closure of the mucosal defect with clips.

All patients were admitted for 24-hour observation following the procedure. They remained nil per os for the first 12 hours. All procedures were performed by a single endoscopist experienced in endoscopic submucosal dissection (ESD) and third-space endoscopy, but without prior experience in other techniques for the treatment of ZD.

Endpoints and definitions

The primary outcomes were technical and clinical success at six months. Technical success was defined as completion of a full cricopharyngeal myotomy and the procedure as per protocol. Clinical success at six months was defined as a Dakkak-Bennett dysphagia score of 1 (or 0 if the pre-procedure score was 1) and KHSS score of 2 without the need for further interventions within six months.

Secondary outcomes included: 1) AEs and their severity, classified according to the American Society for Gastrointestinal Endoscopy (ASGE) criteria; 2) changes in quality of life measured by the MDADI and EAT-10 score; 3) symptom recurrence defined as a dysphagia Dakkak-Bennett score of ≥ 2 more after six months of follow-up in patients who had previously achieved clinical success; 4) the need for reintervention.

Symptom severity was assessed at baseline and at 1, 6 months after treatment in all patients. In those who exceed 6 months of follow-up scores were evaluated again at 12 and 24 months of follow-up.

Dysphagia scores and quality-of life questionnaires can be seen in supplementary material.

Statistical Analysis

Categorical variables were reported as absolute frequencies and percentages, while continuous variables were expressed as medians and ranges or means and standard deviation. The Shapiro-Wilk test was used to determine the normal distribution of the continuous variables. The Wilcoxon test was used to determine the difference in

medians at baseline and 6 months of follow-up. The Wilson method was used to calculate 95% confidence intervals (Cis). Data analysis was performed using IBM SPSS Statistics, Version 20.0 (Chicago, IL) and Microsoft Excel (version 2018; Microsoft, Washington, USA).

RESULTS

Baseline characteristics

A total of 24 patients were included (Table 1). The mean age was 77.5 years (54-98), and 16 patients (66.7%) were male. The mean diverticulum size was 25 mm (± 11.5).

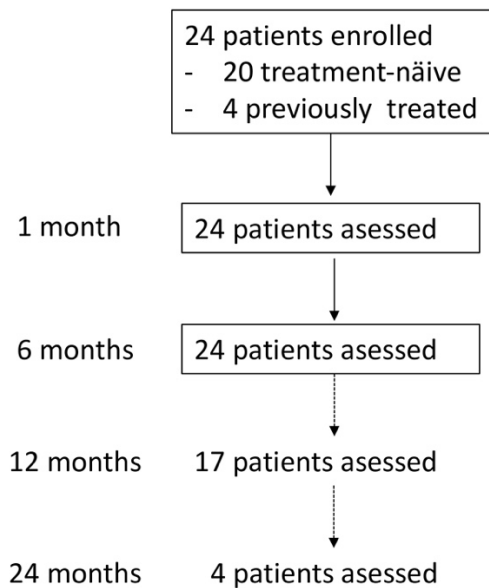
The most common symptoms at the time of the diagnosis were dysphagia (100%) and regurgitation (95.8%). Most patients (66.7%) had a Dakkak-Bennett dysphagia score of 4 at baseline. Among those with regurgitation (n=23), 17 (75%) reported symptoms occurring more than once per day. Additional symptoms included weight loss (29.2%) and halitosis (8.3%).

The mean preprocedure EAT-10 score was 20 (7-40), and the mean MDADI score was 53 (26-90).

Four patients (16.7%) had previously undergone treatment for ZD with rigid endoscopy septotomy assisted using LigaSureTM, two of them more than once (up to three times).

Almost half of the patients were classified as ASA III. The median Charlson Comorbidity Index (CCI) score was 4 (1-7).

Only two patients (8.3%) were on anticoagulation therapy, which was discontinued according ESGE recommendations (10). Six patients (25%) were on antiplatelet medications of whom 83.3% continued treatment during the procedure.



Procedural details

The diverticuloscope was not used in one patient due to difficulty in placement and was removed early in two cases due to inadequate isolation of the diverticulum. A 0.038" guidewire was used in all patients for diverticuloscope placement.

Minor intraprocedure bleeding occurred in two patients (8.3%) and was managed using bipolar hemostatic forceps.

The median procedure time was 36.5 (22-91) minutes, including diverticuloscope placement 5.5 (2-41) minutes, cutting and dissection averaging 18 (6-48) minutes, and incision closure 11.5 (3-34) minutes. Technical difficulties occurred in 8 patients (33.3%), mainly due to fibrosis or unstable endoscope positioning. Closure of the mucosal incision was challenging in two cases (8.3%) due to impaired maneuverability but successfully completed. Procedure times for each step demonstrated a downward trend with increasing endoscopist experience (Figure 2).

Clinical outcomes

Primary Outcomes: Technical and Clinical Success.

Technical and clinical success at 6 months was achieved in 24/24 of patients (100% ; 95% CI 86.2%-100%). Dysphagia, regurgitation and respiratory symptom scores showed marked improvement thereafter (Figure 3a). The median baseline KHSS decreased from 8 (2-11) to 0 (0-4) at 6 months post-procedure ($p<0.001$). At 6 months, 20 of 24 patients (83.3%) had a KHSS of 0; 95% CI 64.2%-93.3%. (Figure 3b). Regurgitation score (score ≥ 2) persisted in two patients, although without dysphagia symptoms and with a substantial gain in quality of life. The mean post-procedure hospital stay was 1 day (1-2), with no readmissions. The median follow-up was 12.2 (6-26.6) months.

Secondary outcomes

No AEs occurred (0%; 95% CI 0%-13.8%), as classified by ASGE guidelines. Quality of life, measured with MDADI score, improved from median basal scores of 53 (26-90) to 95 (71-100) at one month (median 41, IQR 32-49) (2.5; 95% CI 2.08-2.92) and 99 points (65-100) at 6 months (median 41, IQR 36-48) (2.54; 95% CI 2.12-2.96) of follow-up. The EAT-10 score also showed a greater improvement during first days after treatment, starting from a median baseline of 20 (7-40), which decreased to 1 (0-7) at one month (median 16, IQR 13-26) (2.59; 95% CI 3.01-2.17) and 0 (0-4) at six months (median 20, 14-27) (2.66; 95% CI 3.08-2.24). No cases of dysphagia recurrence were observed during follow-up and no reinterventions were required.

DISCUSSION

The results of this study demonstrate that NiZ-POEM is an effective and safe technique for the treatment of ZD. Although several variations of the originally described Z-POEM technique have been developed, there is still no strong evidence demonstrating its clinical superiority or safety profile compared to FES (11). As a result, many endoscopists remain hesitant to adopt third-space techniques, given their greater technical complexity and associated risks.

From a technical perspective, we would like to highlight several specific aspects of the NiZ-POEM technique that represent improvements over previously described Z-POEM approaches and offer advantages compared to standard FES (7,12). First, the authors

emphasize the use of a diverticuloscope, even in the hands of an experienced endoscopist. Its use is justified by the improved exposure it provides, which facilitates the procedure and allows for easy repositioning of the endoscope when necessary. Although diverticuloscope placement may initially increase procedure time, this phase-like other steps in the technique- has a learning curve, once overcome, placement can be performed in just a few minutes. Importantly, once the diverticuloscope is in place, the Z-POEM procedure becomes more accessible even to endoscopists with less advanced technical skills, thereby making this technique more widely adoptable. Second, the NiZ-POEM technique avoids submucosal injection and tunneling on either side of the cricopharyngeal muscle, which contributes to a shorter procedure time. In our series, the median procedure duration was 36.5 minutes (22-91), notably shorter than previously reported in the literature, with Almario JA et al. (6) reporting a mean of 57 minutes (± 34) or Elkholy S et al. (13) with a median of 62 minutes (32-210). However, this streamlined approach relies heavily on precise endoscopic visualization to accurately identify the muscle layer and ensure a safe and complete myotomy. Third, unlike FES, the Z-POEM approach allows for extended myotomy beyond both the fundus and beyond the limits of the mucosotomy. This broader myotomy may contribute to a lower recurrence rate of dysphagia although this hypothesis needs to be validated in prospective comparative studies. Z-POEM times showed a downward trend, while clip placement times were slightly longer. This is likely because, with increasing experience, the mucosal flap mucosotomy procedure tends to take longer, resulting in the use of more clips and consequently, longer placement times. Moreover, the Cumulative Sum Control Chart (CUSUM) analysis revealed a downward trend after the first cases.

The technical success and clinical success rate at 6 months was 100%, despite the inclusion of patients who had undergone previous treatments. Regurgitation persisted in two patients who experienced daily regurgitation but had no dysphagia with any texture. These cases corresponded to the initial procedures, in which a more conservative approach to cricopharyngeal myotomy and additional mucosotomy of residual mucosal flaps was likely adopted due to limited operator experience. In line with these findings, a recent international multicenter study demonstrated that

performing POEM with mucosal flap incision improves dysphagia symptoms in patients with ZD (6). The use of additional mucosal incision for the remaining flaps combined with a tailored myotomy using an objective measurement with the “doble sticker over knife” method described by our group (9), may account for the clinical success achieved in all patients.

It is noteworthy that patient-reported quality of life showed substantial improvement at one month post-procedure, with slower but continued gains in the following months. This finding is likely explained by the development of sitophobia in many patients due to severely limiting preprocedural symptoms, requiring an adaptation period to regain confidence in swallowing during follow-up.

Although Z-POEM is considered a safe procedure with low adverse events rates (2.8-9%) (6,13, 14,15,16,17, 18), our NiZ-POEM approach further improved these outcomes, with no complications reported in our series. This finding is particularly relevant given the advanced median age of our patients (77.5 years, range 54-98) and their associated comorbidities (Charlson Index 4, range 1-7). Since ZD is typically diagnosed in the sixth to seventh decade of life, the primary determinant for treatment should be symptom severity rather than the patient age or comorbidities, especially when a safe and minimally invasive technique such as NiZ-POEM is available. To our knowledge, this study represents the largest consecutive series of patients treated with NiZ-POEM and the first to report systematic outcomes using validated dysphagia and quality-of life scores. Although these results are encouraging, several limitations merit consideration. First, this study represents a single-center experience in which all procedures were performed by a single endoscopist with extensive experience in ESD, potentially limiting the broader applicability of the findings. In this context, the number of patients included was relatively high despite the short inclusion period; this may have contributed to the favorable results obtained and might not be generalizable to low-volume centers. Second, the absence of a control group undergoing FES precludes direct comparisons of the efficacy and safety of NiZ-POEM with standard techniques. Third, the lack of observed recurrence should be interpreted cautiously given the relatively short follow-up duration. Finally, our post-hoc analysis indicated that the study had over 95% power to detect the observed median

differences in the primary outcomes. However, the small sample size may limit the detection of rare adverse events, and these findings should be interpreted cautiously when generalizing to broader populations.

In conclusion, this study demonstrate that NiZ-POEM is a safe and effective technique for the treatment of Zenker's diverticulum, with no recurrences or adverse events. Given its favorable safety profile, neither patient age nor comorbidities should preclude the consideration of NiZ-POEM in symptomatic patients.

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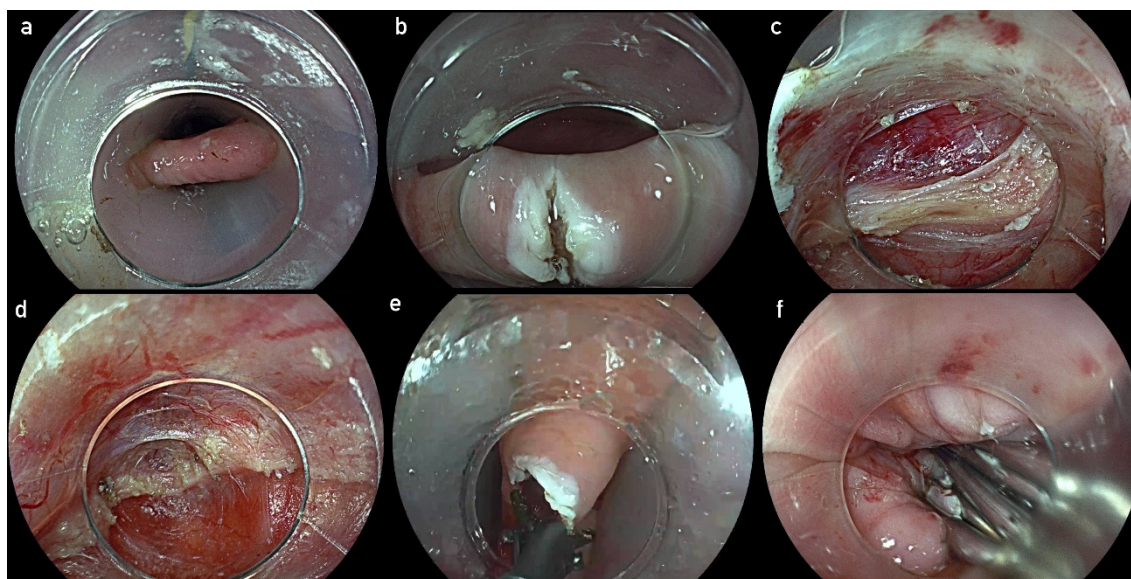


Figure 1: Steps of NiZ-POEM technique for Zenker's diverticulum: A. Diverticuloscope placement over guidewire isolating the cricopharyngeal muscle. B. Mucosal incision over cricopharyngeal muscle. C,D. Cricopharyngeal myotomy under direct view. E. Cut of remaining mucosal flap at esophageal and diverticular sides. F. Clips placement for incision closure.

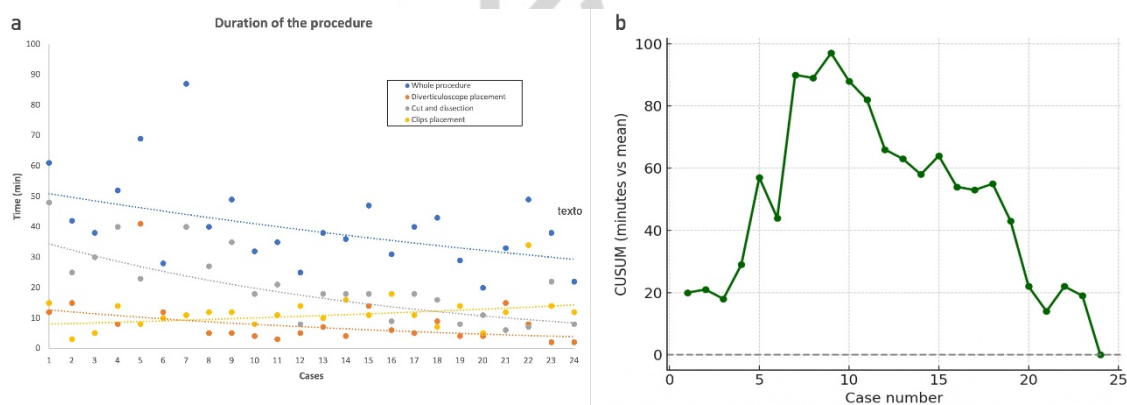


Figure 2: A. Trend in procedure time across the steps of NiZ-POEM. B. Cumulative Sum Control Chart (CUSUM) analysis demonstrates an early downward slope followed by stabilization, consistent with attainment of procedural competence.

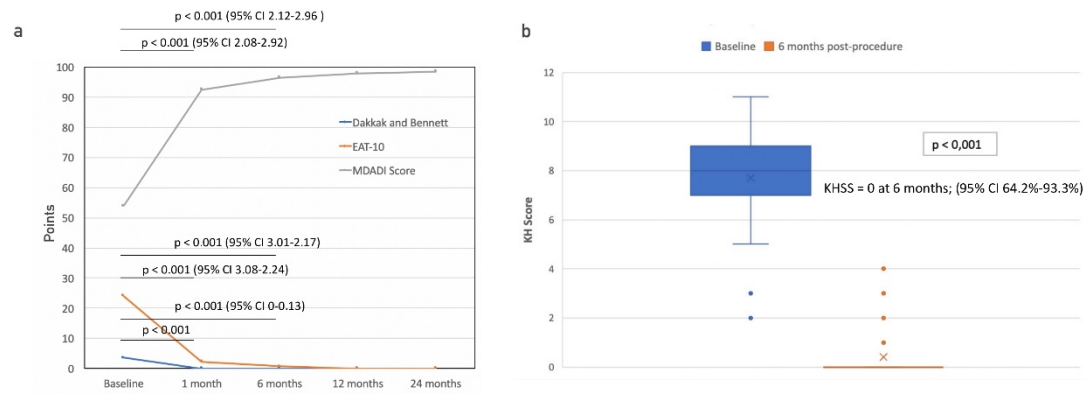


Figure 3: A: Changes in dysphagia (Dakkak-Bennett and EAT-10) and quality-of-life (MDADI) scores following endoscopic treatment. B: Clinical improvement according to Kothari-Haber Score System from baseline to 6-months follow-up.

Table 1: Patient and procedure characteristics of patients who underwent Zenker's diverticulum NiZ-POEM.

<i>Baseline characteristics</i>	N=24
Age (years), median (range)	77.5 (54-98)
Gender, n (%)	
Male	16 (66.7)
Female	8 (33.3)
ASA classification, n (%)	
ASA I	0
ASA II	13 (54.2)
ASA III	11 (65.8)
Charlson Comorbidity Index, median (range)	4 (1-7)
Anticoagulants, n (%)	2 (8.3)
Antiplatelets, n (%)	6 (25)
Previous treatments, n (%)	
Surgery	0
Rigid septotomy (LigaSure™)	4 (16.7)
Number of previous treatments (LigaSure™), n (%)	
1	2 (8.3)
2	2 (8.3)
Diverticulum size (mm), mean (SD)	25 (11.5)
Baseline Dakkak Bennett Score, median (range)	
Dysphagia score	4 (1-4)
Regurgitation score	4 (0-4)
Respiratory symptoms	4 (0-4)
Baseline KHSS, median (range)	8 (2-11)
Baseline EAT-10 Score, median (range)	20 (7-40)
Baseline MDADI Score, median (range)	53 (26-90)
<i>Procedure details</i>	
Diverticuloscope use rate (whole procedure), n (%)	21 (87.5)
Procedure time (min), median (range)	36.5 (22-91)
Diverticuloscope placement,	5.5 (2-41)
Cutting and dissection,	18 (6-48)
Clips placement for closures	11.5 (3-34)

Number of clips used, median (range)	8 (4-12)
Time-to-oral diet 24 hours, n (%)	24 (100)
Hospital stay (days), median (range)	1 (1-2)
Adverse events, median (range)	0
Readmissions, n (%)	0
Follow up (months), median (range)	12.2 (6-26.6)

ASA: American Society of Anesthesiologists; SD: Standard deviation; KHSS: Kothari-Haber Symptom Score; MDADI: MD Anderson Dysphagia Inventory.