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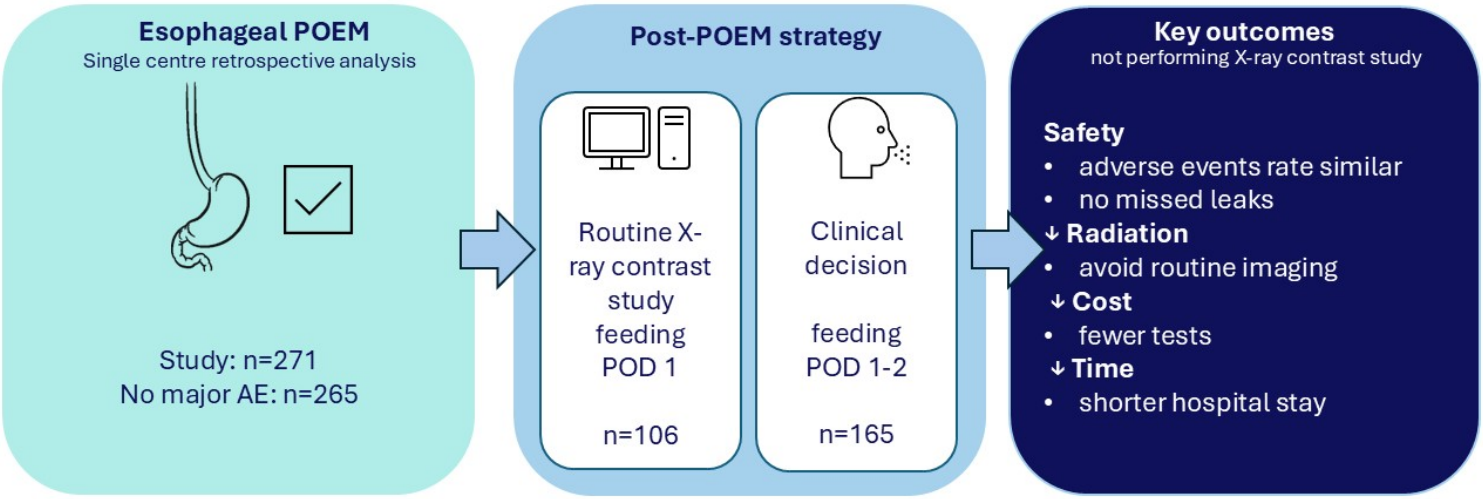

Routine contrast study after uncomplicated POEM may be safely omitted

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Routine X-ray contrast study after peroral endoscopic myotomy does not improve patient outcomes

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List of abbreviations

POEM – peroral endoscopic myotomy

AEs – adverse events

LES – lower esophageal sphincter

PD – pneumatic dilatation

LHM – Heller myotomy

ESGE – European Society of Gastrointestinal Endoscopy

Z-POEM – POEM procedures performed for Zenker diverticulum

G-POEM – POEM procedures performed for gastroparesis

HRM – high resolution manometry

EGJ – esophagogastric junction

D-POEM – POEM of the septum of the diverticulum

CT – Computed Tomography

CDC – Clavien-Dindo Classification

AGREE – Adverse Events Gastrointestinal Endoscopy Classification

Abstract

Study Background and Aim: Peroral endoscopic myotomy (POEM) is a primary treatment for achalasia. Traditionally, oral feeding is initiated after an X-ray contrast study excludes the post-procedure leak. However, since major adverse events (AEs) are rare and typically symptomatic, the need for routine postprocedural X-ray studies is uncertain. Our center initially used routine X-raycontrast studies, but from late 2018 we adopted a clinical decision-based approach, starting oral feeding on postoperative day 2 unless complications were suspected. This study compares both strategies regarding complication rates and

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hospital stay.

Methods: We performed a retrospective analysis of POEM procedures between 2015 and 2023 in our tertiary center. Patients were divided into an "X-ray subgroup" (feeding after negative X-ray contrast study on the 1st postoperative day) and a "clinical decision subgroup (feeding on the 1st or 2nd postoperative day based on a clinical judgment). Primary outcomes were the rate of major and minor AEs and length of hospital stay.

Major Results: A total of 271 POEM procedures were analyzed (129 males, 142 females; mean age 52.6 ± 16.1 years). X-ray contrast was performed in 106 (39.1%) patients (March 2015 – December 2018), while in 165 (60.9%) patients (December 2018 – December 2023) the initiation of oral intake was based on a clinical evaluation. Adverse events occurred in 16 patients (15.1%) and 25 patients (15.2%) in the X-ray group and in the clinical decision group, respectively (p=NS). Major adverse events occurred in 4 (3.8%) and 2 (1.2%) in X-ray subgroup and clinical decision subgroup, respectively (p=NS). Hospital stay was shorter in the clinical decision group. (6.6 ± 1.5 vs. 7.2 ± 2.9 days, p=0.05 95% CI [0.0, 1.2]).

Conclusions: Severe complications after POEM are rare. Routine X-ray contrast study after POEM does not lead to decreased rate of adverse events.

Keywords: Achalasia. Motility. POEM. Adverse events. **C**omplications.

Lay Summary

Peroral endoscopic myotomy (POEM) is a modern endoscopic procedure used to treat an esophagus disease called achalasia, in which food does not pass easily into the stomach. After this procedure, an X-ray examination with contrast medium is usually performed to check for complications, such as leakage of contents outside the esophagus, a situation in which eating is not allowed. When no such leakage is detected, it is possible to start with oral feeding.

However, at our hospital, we have found that such an examination is not always necessary. We therefore compared two groups of our patients:

- one group underwent a routine X-ray examination after the POEM procedure;
- the other group began eating based on their condition – without an X-ray.

We found that serious complications were very rare in both groups. When comparing these two groups, we found that X-ray group did not have fewer complications. Routine X-ray did not lead to safer initiation of eating and did not prevent complications. Contrarily, patients that began eating based on their condition – without an X-ray had fewer complications and slightly shorter hospital stay, most probably because we gained higher proficiency in the procedure. Our study shows that it is safe to omit a routine X-ray and decisions about eating can be made based on their health status instead.

Authorship Declaration according to CRediT Standards

All authors meet the ICMJE authorship criteria.

PB and MDu conceived the study and designed the methodology. MDe and MDu performed the procedures. MV, LN, JV and SP conducted the investigation and contributed to data acquisition. MV, SP, and JV performed the formal analysis and interpretation of the results. MV and MDu drafted the original version of the manuscript. Supervision of the study was provided by MDe and PB. ZT and AD contributed to the critical review and editing of the manuscript.

All authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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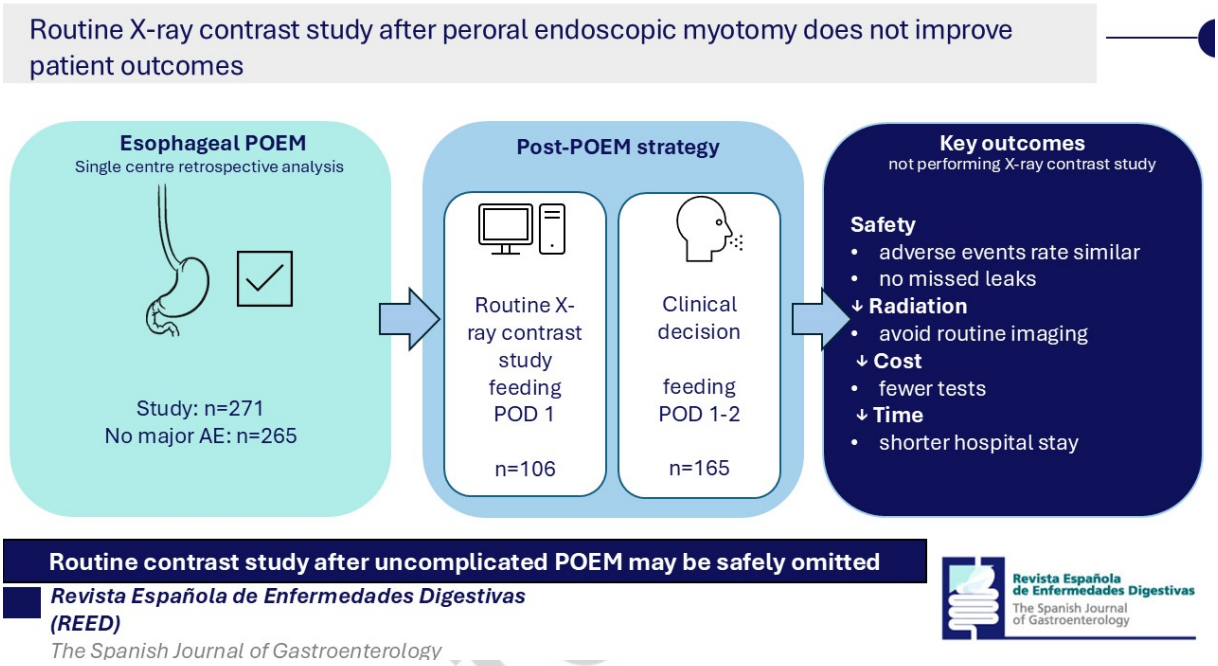
Visual Abstract



Key Points

- Routine X-ray contrast study after POEM rarely detects complications that are not already suspected based on the symptoms.
- Serious complications after POEM are uncommon and usually identifiable without imaging.
- Not performing X-ray contrast study after POEM did not lead to higher incidence of adverse events

Statement of Interests

The authors declare that they have no conflict of interest.

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Ethics Approval

The study was approved by the Ethics Committee of Jessenius Faculty of Medicine in Martin, Comenius University in Bratislava (Code of Ethic committee: EC54/2025; October 10, 2025).

Statement of Generative AI and AI-assisted Technologies in the Writing Process

AI-assisted technologies were not used during the writing process. AI was used to increase the resolution and quality of the images.

Data Availability Statement

Data supporting the study findings are available from the corresponding author upon request.

Introduction

Achalasia is a primary motor disorder of the esophagus with the loss of propulsive peristalsis and impaired relaxation of the lower esophageal sphincter (LES). Typical symptoms include dysphagia, regurgitation, and non-cardiac chest pain (1). The primary therapeutic objective is to enhance the passage of ingested food into the stomach and alleviate these symptoms. Currently(2), POEM has already become the mainstay of treatment of achalasia(3).

The procedure is performed under general anesthesia and constitutes of the creation of the mucosal incision, submucosal tunneling towards the gastric cardia and endoscopic myotomy of the esophageal smooth muscle in the distal esophagus, including the LES, followed by the closure of the mucosal entry with endoscopic clips(4).

Since the introduction of POEM, studies have proven overall safety of the procedure, although the complications rate varies (5-11). This variability is mostly due to different reporting systems used as the incidental finding of pneumoperitoneum or pneumomediastinum on imaging contributed to high-incidence complication rate. This, however, does not affect patients' outcome (12) and is not considered complication

anymore (5). Safe initiation of oral feeding remained essential, with emphasis on verifying mucosal integrity via X-ray contrast study on postoperative day (POD) 1(13). For the same reason upper endoscopy was performed in several studies (9, 11, 14).

Gaining more experience with POEM and confirming low incidence of severe complications led to decreased adherence to routine X-ray studies (15). Indeed, the European Society of Gastrointestinal Endoscopy (ESGE) guideline states that routine X-ray contrast study or endoscopy performed to check the mucosal integrity might be an excessive prophylactic measure of a debatable value (16) as major AEs are rarely asymptomatic. Therefore, altered clinical status of the patients is more important for the diagnostic evaluation than the incidental finding on the X-ray study.

After we started performing POEM in 2015, we routinely performed an X-ray contrast study prior to the initiation of oral feeding until December 2018, when it became unavailable. Then we adopted a strategy of initiating oral feeding based on a clinical decision. As there is an ongoing debate whether to perform the X-ray after POEM or not, we performed a retrospective evaluation of these two strategies. We compared them in terms of the periprocedural and postprocedural complications and the length of the hospital stay.

Patients and Methods

This is a retrospective review of prospectively collected database of POEM procedures performed in the high-volume center (March 2015 – December 2023). The indications for POEM was achalasia. POEM procedures performed for Zenker diverticulum or gastroparesis were not included in the analysis. The study was approved by the Ethics Committee of the Jessenius Faculty of Medicine in Martin, Comenius University in Bratislava with protocol number EK 54/2025.

POEM Procedure

All POEM procedures were performed during hospitalization in general anesthesia with orotracheal intubation. We used an HD endoscope (Pentax 2990i or Olympus HQ190) with

transparent cap (Fuji-film DH-28GR) and an electrosurgical unit (VIO ERBE 300D). Triangular tip knife (TT-knife KD-640L, Olympus) was used for the mucosal entry, submucosal tunneling (after instillation of submucosal space with 0.2% indigocarmine solution) and myotomy. In anterior POEM we performed 16cm long tunneling and 14cm long myotomy (of which 4cm in the stomach). In posterior POEM we performed 12cm long tunneling and 10cm long myotomy (of which 2cm in the stomach). For hemostasis and coagulation of vessels we used hemostatic forceps (FD-410 LR, Olympus). Mucosal entry-point was sealed with hemostatic clips (EZ clip Olympus HX-610-135L, Resolution 360 clip Boston Scientific, Lockado clip MicroTech Endoscopy). Before and after the procedure the patients prophylactically received 3 doses of broad-spectrum antibiotics (metronidazole, cefuroxime). All procedures were performed with CO_2 insufflation. Until March 2022, a single endoscopist was present at the procedures (MDe), since then, until December 2023 two endoscopists were present at the procedure (MD, MDu).

Postprocedural Management

A iodine-based X-ray contrast study was performed on POD 1 and oral intake was initiated unless a leakage of the contrast was detected (clear liquids on POD 1/2, liquid and semi-liquid diet afterwards). Since December 2018 the X-ray contrast study has become unavailable and oral intake was initiated on POD 1/2 based on the clinical decision. The liquid diet was usually started on POD 2 and semi-liquid diet on POD 3/4 and the patient was discharged on POD 4/5. Having gained experience we started clear liquids diet on POD 1 and semiliquid diet on POD 2/3 with discharge on POD 3/4. In the case of more pronounced postoperative pain or based on the endoscopists' recommendation in case of minor adverse events we postponed the initiation of oral diet accordingly. .). Patient was discharged once asymptomatic and tolerating semi-liquid diet. All patients were recommended upper endoscopy 3 months after the procedure as a follow-up.

Outcomes

The primary outcome was the rate of periprocedural and early postprocedural (within 2 weeks after the procedure) AEs. We classified the AEs as major and minor as proposed by Nabi (17) (Table 1). Secondary outcomes included the requirement of repeat endoscopy and the length of hospital stay. Also, we recorded the rate of delayed complications in 3 months follow-up.

Statistical analysis.

Data are presented as mean values±standard deviation. Comparisons were made using Fisher's exact or Welch's two-sample t-test in case of continuous variables. Differences were considered statistically significant at $p<0.05$. Results of multivariable binary logistic regression analysis are presented as adjusted odds ratios (aORs) with 95% confidence intervals (CI), statistical significance was assessed using two-sided tests with $p<0.05$. Analyses were performed in the Jamovi open-source software (Version 2.6) [Computer Software] - https://www.jamovi.org.

Results

Patient description is summarized in Table 2. We evaluated 271 POEM procedures (129 males, 142 females) with the mean age of the patients 52.6±16.1 years. X-ray contrast study was performed in 106 patients (39.1%) (March 2015 – December 2018), in 165 patients (60.9%) oral intake was initiated based on a clinical decision (December 2018 – December 2023) In 2017 and 2018, 7 and 6 patients, resp. did not receive the X-ray contrast study and therefore are included in the clinical decision group (Table 4). All procedures that were carried out at our center were included into the evaluation.

Periprocedural and Early Postprocedural Adverse Events.

Adverse events are summarized in Table 3. A total of 42 AEs (15.5%) were detected of which 6 (2.2%) were considered major and 36 minor (13.3%). Incidence of major and minor adverse events per year is shown in Table 4 and incidence according to the experience phase in Table

5. Major adverse events declined over time – in the first, intermediate and late third of our experience the incidence of major AEs was 4 (4.4 %), 2 (2.2 %) and 0 (0%) of the procedures. The rate of minor adverse events remained relatively unchanged (Table 5). Multivariable binary logistic regression analysis was performed to identify the risk factors independently associated with the overall complications (major and minor). The model included the following covariates selected a priori based on the clinical relevance: age, sex, procedure year, X-ray contrast study, achalasia type and myotomy orientation. We compared the odds of developing the complications across patient groups. A one-year increase in age was associated with higher odds of complications (OR 1.03, 95% CI 1.01 to 1.06, p=0.014). POEM orientation was also associated with the increased odds (OR 2.75, 95% CI 1.20 to 6.28, p=0.007) of post-interventional complications. Both associations remained significant after the adjustment for other confounders aOR 3.65 (95% CI: 1.15 to 11.55 p=0.028) and 1.03 (95% CI: 1.01 to 1.06 p=0.007). Sex, year of procedure, achalasia subtype or X-ray contrast study were not significantly associated with the post-interventional complications (Table 6).

In the X-ray group there were 17 AEs (16%), of which 4 were major and included 3 postprocedural and 1 periprocedural event (labeled as Patient X1-4).

Major Postprocedural AEs:

Patient X1. X-ray contrast study on postoperative day 1 revealed a post-procedure leak due to a loosened mucosal clip; additional endoscopic clips were placed. No further leakage or clinical deterioration occurred. Patient X2 developed melena and hematemesis with hemodynamic instability on POD 10 and was admitted to local hospital. After hemodynamic stabilization the patient was transferred to our ward. Endoscopy revealed bleeding from the site of an unsuccessful mucosal entry with the visible vessel (Forrest IIa), without ongoing bleeding. Multiple hemostatic clips were placed without bleeding recurrence. Patient X3 was readmitted on the POD 13 with retrosternal pain and dysphagia. Endoscopy revealed the ulceration 1 cm above Z-line, X-ray contrast study showed a leak of the contrast fluid in the distal esophagus. No fever and/or leukocytosis were present. The patient received parenteral nutrition, proton pump inhibitors i.v. and was discharged after 8 days tolerating

semi-liquid diet. Importantly, the X-ray contrast study on POD 1 showed no leakage.

Major Periprocedural AE.

Patient X4. After periprocedural perforation of the gastric fundus mucosa (solved by endoscopic clipping) X-ray contrast study revealed a post-procedure leak. Patient received nasogastric tube and prolonged antibiotics until the X-ray contrast study showed no leak. By that time, the patient was asymptomatic, the perforation required no surgery and was discharged on POD 12 (Fig. 1).

Taken together, the X-ray contrast study detected post-procedure leaksin 2 patients (X1 and X4), failing to detect leak on POD 1 in patient X3 in whom leak developed later and was subsequently confirmed by CT based on the clinical suspicion. This results in the sensitivity of 67%.

13 AEs were classified as minor and included 7 mucosal injures that were closed endoscopically, 4 cases of fever requiring extra days of antibiotics and 2 insufflation related AEs (tension pneumoperitoneum) requiring periprocedural drainage (Table 3).

In the clinical decision group AEs were documented in 25 patients (15.2%), of which 2 were major AEs (1.2%) (Patient C1-2 below).

Patient C1. Periprocedural mucosal perforation occurred during POEM with the impossibility to be solved endoscopically and requiring surgical intervention (Fig. 2). A right thoracotomy was performed and 15x10 mm perforation verified 13 cm from the gastroesophageal junction. It was managed with primary esophageal suturing in two layers using braided coated Vicryl. The suture line was covered with a parietal pleural flap and tissue adhesive. Duplex chest drainage was established. On POD 7 the X-ray contrast study showed no leakage. The patient was discharged on POD 12. In Patient C2 perforation with pleural effusion was detected on CT scan, performed due to a new onset of cough. The 1st contrast CT scan on POD 2 did not show any leak, however, CT scan on POD 4 revealed distal esophagus leak and the large volume left pleural effusion (Fig. 3). The condition required left thoracotomy and intraoperative revision revealed signs of mediastinitis. A 5 mm perforation at the esophageal

hiatus was identified and managed with a primary two-layer braided, coated Vicryl sutures. Duplex chest drainage was established. On POD 7, a contrast CT esophagogram demonstrated no extraluminal leakage and the patient was discharged on POD 20.

23 AEs were classified as minor and included 14 cases of insufflation related AEs requiring drainage (tension pneumoperitoneum in all cases), 8 cases of mucosal injures closed endoscopically and 1 case of fever requiring extra days of antibiotics (Table 3).

There was no statistically significant difference between the overall, major and minor AEs in the X-ray group and in the clinical decision group (Table 3). In the X-ray group, 3 of 4 major complications included post-procedure leaks and 2 of them were detected on the X-ray contrast study performed on POD 2. In the clinical decision group, 1 post-procedure leak was detected on CT scan. Not performing the X-ray did not increase the rate of major AEs.

Repeat Endoscopy, Length of the Hospital Stay and Delayed Complications

The mean length of hospital stay was significantly longer in the X-ray group compared to the clinical decision group (7.2±2.9 days vs. 6.6±1.5 days, p=0.05, 95% CI [0.0, 1.2]), most probably due to greater caution in postprocedural management in the first procedures. Omitting the X-ray did not lead to longer hospital stay.

238 patients (87.8%) presented themselves in the endoscopic check-up (93% from the X-ray subgroup and 84.3% from the clinical decision subgroup) 3 months after POEM. 1 female patient developed a delayed complication (0.37%). The patient was readmitted after 35 days after POEM due to dysphagia, noncardiac chest pain and cough with subfebrile condition. Endoscopy revealed a fistula opening in the distal esophagus, the CT scan confirmed the pleuroesophageal fistula. This patient belonged to the X-ray group and had a minor postprocedural complication: during the POEM hospitalization she developed fever without hemodynamic instability due to mediastinitis. This was confirmed on the CT scan on POD 5, managed conservatively with antibiotics and the patient was discharged on POD 14. Importantly, the X-ray contrast study on POD 1 showed no post-procedure leak.

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Discussion

The main results of our study confirm that omitting a routine X-ray contrast study after POEM did not increase the adverse event rates. The clinical decision group required a lower number of repeat endoscopic procedures and no delayed complications. Additionally, the hospital stay was shorter in this group with marginal statistical significance.

A wide range of AE rate after POEM is reported because of various classification systems. The most frequent AEs include insufflation related conditions, such as pneumothorax or pneumomediastinum. These do not require treatment and therefore are not considered true AEs (17). Major complications, such as esophageal post-procedure leak are rare (5, 17, 18). We used the classification proposed by Nabi (17) as other systems (Clavien-Dindo (CDC) (18), ASGE lexicon's severity grading system) are more universal and not adjusted to the specifics of the POEM procedure (19).

The studies performed so far report overall complication rates of 5-7% using routine X-ray contrast studies (5, 15), others document AE rates of 9-14% with the routine CT esophagogram (6, 20) and there are also reports on a safe oral intake initiation without imaging with complication rates of 1.2-6% (21, 22). We consider our findings of 3.8% and 1.2% AEs in the X-ray group and in the clinical decision group, resp. consistent with the abovementioned results. A landmark study reported 7.5% of AEs (0.5% of severe AEs) (5) using ASGE lexicon's severity grading system which includes any symptomatic event, even anesthesia-related, that interrupts the procedure or requires management. Therefore, acute conditions (cardiac arrythmias, pneumonia, etc.) were included, unlike strictly procedure-related Nabi´s system. A randomized controlled trial reported no serious AEs after POEM (23). A retrospective analysis compared two reporting systems (Clavien-Dindo classification and ASGE lexicon's classification) (6). According to both classifications there was 9.4% complication rate. We consider the rate of our major AEs consistent with the abovementioned studies. A recent retrospective analysis has similar design to ours and used the Adverse Events Gastrointestinal Endoscopy Classification (AGREE) system to compare the groups with and without the routine post-POEM X-ray contrast study (21). The study reports similar outcomes to ours. Their rate of all adverse events was 10.8% (somewhat

lower than ours), however, the rate of major post-procedural AEs of grade II was 0.9% (in both groups) and of grade IIIa 1.4% (1.6% and 1.3% in the abovementioned groups, resp.), which was similar to our study The main outcome was the same as in the present study – abandoning the routine X-ray contrast study did not lead to an increased complication rate. Also, no AEs were associated with the post-procedure leak when no X-ray was performed, unlike our study where 1 AE was related to the post-procedure leak in the clinical decision group (C2).

Another aspect of our data is the ability of X-ray contrast study to detect complications the early intervention of which would improve the patients' outcome. In the present study, of 4 major AEs, the X-ray contrast study detected 2 post-procedure leaks on POD 1 that changed the patient management (X1 and X4) and detection of 1 post-procedure leak was delayed and based on clinical suspicion (X3), resulting in 67% sensitivity. On the other hand, major complications in the clinical decision group were detected intraprocedurally (C1) and postprocedurally (C2 – CT scan on POD 4 due to new onset of cough) and there was no other patient with underdiagnosed clinically significant post-procedure leak. A study evaluating the utility of the X-ray contrast study reported 2 (2.6%) complications (contained post-procedure leak and subcutaneous emphysema) in symptomatic patients, that prompted intervention (24). Contrary to their results, in the present study, 2 post-procedure leaks occurred in asymptomatic patients in the X-ray group (X1, X4).Same study also reported that most of the findings are clinically insignificant (21). Reddy et al. shows similar rates of post-procedure leaks as the present study. Of 170 patients in their study, the X-ray contrast study or CT esophagogram correctly identified leak in 2 patients and it was negative in 2 other patients until clinical deterioration occurred. In the present study, of 106 patients, the X ray contrast study correctly identified post-procedure leak in 2 patients and in 1 patient after the clinical deterioration. As seen, the X-ray contrast study might confirm abnormal findings when clinically suspected, but also might lead to false-positive results with potentially unnecessary intervention and false-negative results with a consequence of delayed complications. Although as high as 100% sensitivity was reported (24), in our study it was only 67%. Also, false-positive X-ray contrast studies for esophageal leak occur, corresponding to low specificity of 45-62% (24, 25).

The hospital stay was shorter with marginal statistical significance in the clinical decision group compared to the X-ray group in the present study. We ascribe this to the increased expertise in POEM procedure which translates into earlier safe discharge and fewer major complications requiring extension of the hospital stay (Table 5). Indeed, the X-ray contrast study became unavailable after ~100 procedures corresponding to completion of the learning curve. We consider the procedural experience to be more critical for safety than post-procedure imaging. Still, the duration of the hospital stay in our study is longer than in the most of the previous studies. Although some of them report median length of hospitalizations 4 days (26), there is increasing evidence of safety of the same-day or early discharge, both in adults (22, 27, 28) and in children (29) Indeed, a retrospective study evaluating the same-day discharge suggests its safety, unless more severe complications (>II according to the AGREE system) emerge. The need for impatient care is therefore questioned as this strategy seems safe with low readmission rates (27), potentially reducing healthcare costs. On the other hand, close follow-up monitoring after the procedure and adequate pain management while outpatient is required. There are couple of explanations for the longer hospital admission in the present study. Our local practice is to admit the patients 1–2 days before the procedure to arrange anesthesia preoperative evaluation. For safety purposes, patients are not discharged earlier than on POD 3 considering the unsatisfactory erudition in the procedure and its complications in some regions of the country and lack of experience with potential complications. Extension of the hospital stay under these circumstances is also supported by the recent expert review (30). There are only 2 centers performing POEM in the country and the availability of the thoracic surgery backup is limited. Also, reimbursement issues play role.

Our study has limitations. Firstly, the design of the study was retrospective. There was no standardized protocol for the initiation of oral feeding according to the postprocedural day, which could add to the variability of the alimentation strategy and lead to less precise data on the hospital stay. The adherence of the patients to follow-up was not checked systematically. Single-center design limits the generalizability of our outcomes. Second, we analyzed all procedures, including those performed at the time of gaining experience. This was because we wanted to reflect the real-life POEM training conditions. Thirdly, with 87.8%

adherence to the 3 months follow-up, we cannot exclude delayed complications in patients lost to follow-up.

Conclusion

Our study contributes to the evidence that infrequence of postprocedural AEs makes its clinical utility debatable. Most of AEs are minor, whereas the detection of major AEs is rather based on clinical suspicion than preventive measures. We suggest that X-ray study after POEM is not performed routinely, and that its use is reserved for specific situations when integrity of the mucosal entry needs to be verified. Instead, a CT scan with oral contrast should be used if the condition of the patient after POEM deteriorates.

Key points box

• **What was previously known**	• **What this study adds**	• **How this may affect clinical practice**
• Routine X-ray contrast studies are often used after POEM to detect post-procedure leaks before restarting oral intake.	• Clinical decision-based approach without routine X-ray is safe and does not increase adverse events.	• Routine X-ray may be omitted in most POEM cases, allowing earlier feeding and earlier discharge

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Table 1. Adverse events with POEM. The classification system of adverse events adopted from Nabi (17).

Classification of adverse events with POEM	
Major	**Minor**
Insufflation related adverse events leading to:	**Insufflation related**
• hemodynamic instability	• requiring drainage
• premature termination of the procedure	• temporary withholding procedure
Bleeding (intra-operative or delayed)	**Mucosal injury**
• requiring blood transfusion	• closed endoscopically
• associated with hemodynamic instability	**Fever**
• requiring reintervention	• requiring extra days of antibiotics
Mucosal injury	
• requiring special closure techniques	
• prolonged hospital stay	
Post-procedure leak	
Fever/sepsis	
• associated with hemodynamic instability	

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Table 2. Patient description. Results are presented as n (%).

	Total (N=271)	**X-ray subgroup (N=106)**	**Clinical decision subgroup (N=165)**
Males	129	50	79
Females	142	56	86
Age	52.6±16.1	52.3±16	52.8±16.2
Achalasia type I.	79 (29.2)	28 (26.4)	51 (30.1)
Achalasia type II.	116 (42.8)	44 (41.5)	72 (43.6)
Achalasia type III.	12 (4.4)	8 (7.5)	4 (2.4)
Unable to classify	15 (5.5)	6 (5.7)	9 (5.5)
Previous intervention for achalasia	49 (18.1)	20 (18.9)	29 (17.6)
Anterior POEM	237 (87.5)	87 (82.1)	150 (90.1)
Posterior POEM	34 (12.5)	19 (17.9)	15 (9.9)

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Table 3. Incidence of total, major and minor adverse events in the X-ray subgroup and in the clinical decision subgroup separately. Values are reported as n (%). Significance of difference between the X-ray subgroup and clinical decision subgroup is reported where relevant.

	Total (N=271)	**X-ray subgroup (N=106)**	**Clinical decision subgroup (N=165)**	**Detection method**	**p value**
Major adverse events	6 (2.2%)	4 (3.8%)	2 (1.2%)		NS
— bleeding	1 (0.4%)	1 (0.9%)	0 (0%)	clinical evaluation (X2)	
— mucosal injury	1 (0.4%)	0 (0%)	1 (0.6%)	periprocedural (C1)	
— post-procedure leak	4 (1.5%)	3 (2.8%)	1 (0.6%)	X-ray contrast study (X1, X3, X4), CT after clinical suspicion (C2)	
Minor adverse events	36 (13.3%)	13 (12.3%)	23 (13.9%)		NS
— insufflation related	16 (5.9%)	2 (1.9%)	14 (8.5%)		
— mucosal injury	16 (5.9%)	7 (6.6%)	8 (4.8%)		
— fever	4 (1.5%)	4 (3.8%)	1 (0.6%)		
All adverse events	42 (15.5%)	17 (16.0%)	25 (15.2%)		NS
Repeat endoscopy	4 (1.5%)	3 (2.8%)	1 (0.6%)		NS
Follow-up endoscopy	238 (87.8%)	100 (94.3%)	138 (83.6%)		
Delayed adverse events	1 (0.4%)	1 (0.9%)	0 (0%)		
Hospital stay (days)	6.8±2.2	7.2±2.9	6.6±1.5		0.05

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Table 4. Distribution of major and minor adverse events according to calendar year throughout the study period. Values are reported as n (%). In 2017 and 2018, 7 and 6 patients, resp. did not receive the X-ray contrast study and therefore are included in the clinical decision group. None of these patients experienced complications.

		X-RAY subgroup				**Clinical decision subgroup**							
Adverse event	**Type**	2015	2016	2017	2018	2017	2018	2019	2020	2021	2022	2023	Total
Major	**Mucosal injury**							1					1
	Post-procedure leak	3								1			4
	Bleeding				1								1
Major Total		3			1			1		1			6
Minor	**Fever**	1		1	1				1				4
	Insufflation related			1	2				2		6	5	16
	Mucosal injury	1		5	2				5		1	2	16
Minor Total		2		7	5				8		7	7	36
Grand Total		5		6	6			1	7	1	7	7	42
Number of POEMs		26	18	33	29	7	6	12	26	25	50	39	271
% of AEs		19,2 %	0,0 %	18,2 %	20,7 %	0,0 %	0,0 %	8,3 %	26,9 %	4,0 %	14,0 %	17,9 %	15,5 %

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Table 5. Adverse events stratification after dividing the study to thirds based on the number of cases to early, intermediate and late experience. Values are reported as n (%). Unlike minor adverse events, incidence of major adverse events gradually declined towards the late period.

Period	POEM (n)	Major	Minor	Total
Early	1st - 90th	4 (4.4%)	11 (12.1%)	16 (17.6%)
Intermediate	91st - 180th	2 (2.2%)	11 (12.2%)	12 (13.3%)
Late	181st - 271st	0 (0.0%)	14 (15.6%)	14 (15.6%)
Total	271	6 (2.2%)	36 (13.3%)	42 (15.5%)

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Table 6. Multivariable binary logistic regression analysis. Results are presented as adjusted odds ratios (aORs) with 95% confidence intervals (CI). The model included covariates selected a priori based on clinical relevance: age, sex, procedure year, X-ray contrast study, achalasia type and myotomy orientation. Posterior myotomy and age showed statistical significance.

	Unadjusted OR (95% CI)	**p**	**Adjusted OR (95% CI)**	**p**
Procedure year (per 1 year)	1.00 (0.89 - 1.14)	0.953	1.05 (0.82 - 1.36)	0.682
Orientation: Posterior vs Anterior	2.75 (1.20 - 6.28)	0.014	3.65 (1.15 - 11.55)	0.028
Achalasia type II. vs I.	0.94 (0.42 - 2.11)	0.889	0.92 (0.40 - 2.09)	0.835
Achalasia type III. vs I.	0.50 (0.06 - 4.24)	0.525	0.39 (0.04 - 3.48)	0.401
Achalasia after intervention vs I.	1.21 (0.47 - 3.12)	0.697	0.57 (0.17 - 1.93)	0.367
Achalasia unable to classify vs I.	0.39 (0.05 - 3.27)	0.388	0.23 (0.03 - 2.11)	0.194
Age (per 1 year)	1.03 (1.01 - 1.06)	0.007	1.03 (1.01 - 1.06)	0.007
Sex: male vs female	0.88 (0.45 - 1.74)	0.721	1.08 (0.53 - 2.19)	0.835
X-ray: Yes vs No	1.04 (0.53 - 2.07)	0.901	1.25 (0.32 - 4.83)	0.750

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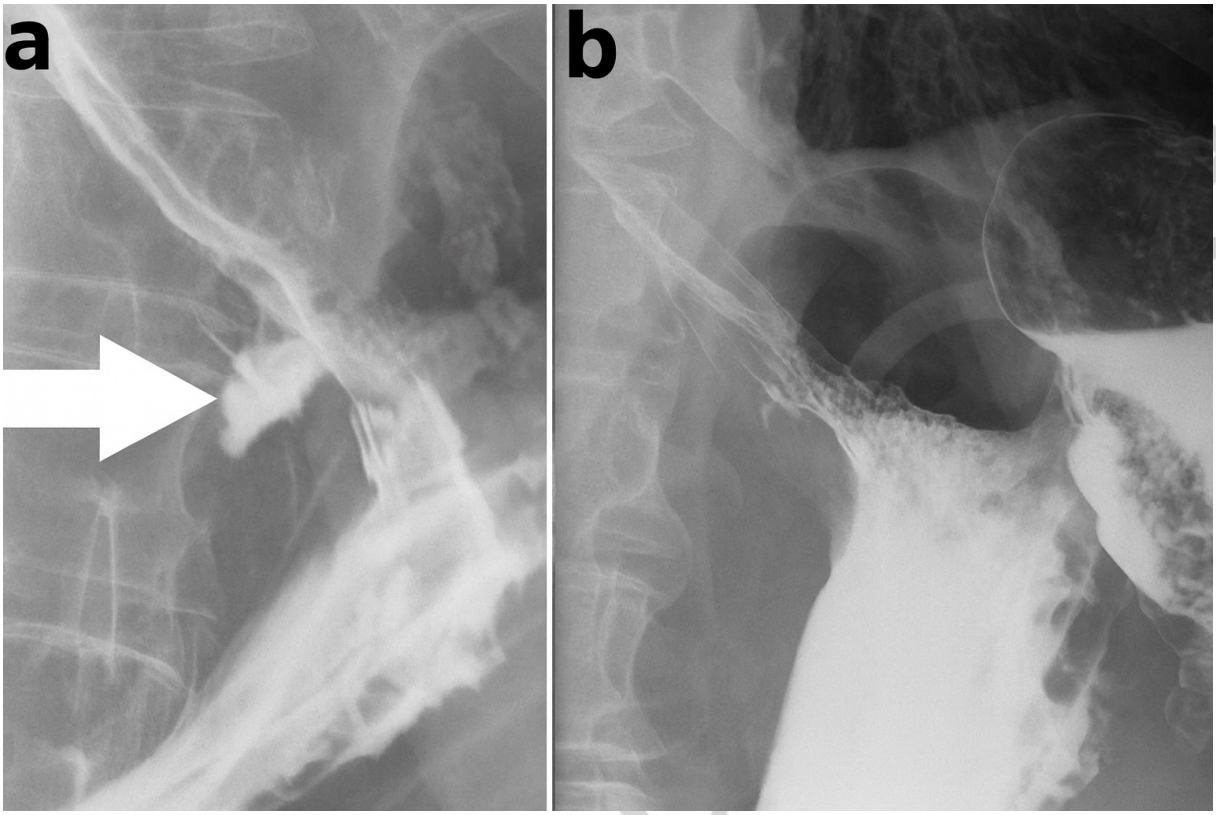

Fig.1 Patient X4. a) X-ray contrast study on 1st postoperative day using water-soluble iodine contrast agent showing post-procedure extraluminal and intramural leak in subcardial region (arrow). b) Check-up X-ray contrast study on 10th postoperative day showing regression of the finding.

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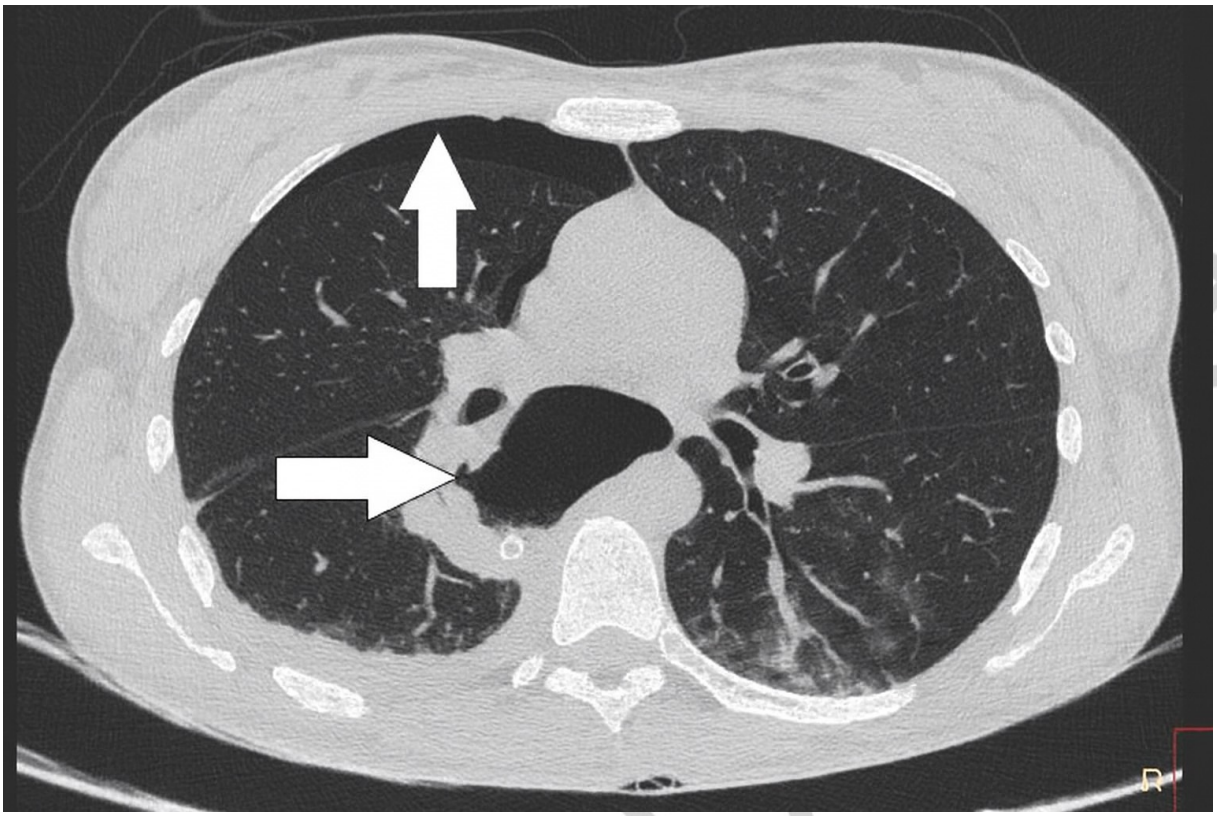

Fig.2 Patient C1, native chest CT on the day of POEM procedure, axial plane, lung window. Defect in the esophageal wall (horizontal arrow) after perforation at the level of the mucosal incision and right-sided pneumothorax (vertical arrow).

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Fig.3 Patient C2, 4th postoperative day CT esophagogram with intravenous contrast detected communication between the distal esophagus and the left pleural cavity with its leakage from esophagus.