Endoscopy versus radiology in post-procedural monitoring after peroral endoscopic myotomy (POEM)

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Abstract

Background The newly developed technique of peroral endoscopic myotomy (POEM) has been shown to be effective in several short- and mid-term studies. Limited information is available about the adequacy of immediate post-POEM monitoring tests.

Methods POEM was performed under general anesthesia in 228 patients (59.6% male, mean age 45.6 ± 15.5 years). Post-procedural checks comprised clinical and laboratory examination, and, during post-procedure days 1–5, endoscopy and—in the first 114 cases—radiologic examination using water-soluble contrast (1st group); the remaining patients underwent post-procedure controls without radiology (2nd group). Main outcome was value of endoscopic compared to radiologic control for recognition of early adverse events.

Results In the first group, routine fluoroscopic contrast swallow suggested minor leakages at the mucosal entry site in two cases which was confirmed endoscopically in only one. Endoscopy revealed two minor entry site leakages and, in six additional cases, dislocated clips without leakage (overall 5.3%). All eight patients underwent reclipping and healed without clinical sequelae. In the 2nd group, endoscopy showed 5 clip dislocations (all reclipped) and one ischemic cardiac perforation in a patient with clinical deterioration on post-POEM day 1 who had to undergo surgery after confirmation of leakage by CT.

Conclusions Radiologic monitoring (contrast swallow) after POEM is not useful and can be omitted. Even routine endoscopic monitoring for detection and closure of minor defects of the mucosal entry site yields limited information with regards to final outcome; major complications are very rare and probably associated with clinical deterioration.

Clinical Trials Gov Registration number of the main study: NCT01405417.

Keywords Achalasia · Peroral endoscopic myotomy · Complications · Post-procedure follow-up

Abbreviations

CI Confidence interval
CrP C-reactive protein
ESD Endoscopic submucosal dissection
EGJ Esophagogastric junction

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Peroral endoscopic myotomy (POEM) for the treatment of primary achalasia combines the scarless endoscopic approach with the surgical principle of myotomy and has aroused great interest [1–4]. A large number of case series and studies from Europe, Asia, and the US have shown promising results with mostly short follow-up. They have been summarized in multiple systematic reviews and meta-analyses [5–9]. Mid-term results have been somewhat variable [10–12]. Reported complication rates have been generally low with regards to major adverse events [13–19], while the frequency of minor complications has been quite variable, mostly due to a lack of uniform definitions [13]. Nevertheless, POEM has a substantial potential for complications during and after the procedure. The latter may come either from inadequate closure of the mucosal entry site in the POEM procedure, or from transmural leakage because of ischemic damage to the mucosa overlying the myotomy. These could lead to serious harm from infection and mediastinitis. Therefore, the full spectrum of post-procedural POEM monitoring primarily includes clinical and laboratory checks as well as endoscopic and radiologic examinations; the latter could include contrast swallow as well as routine CT. However, the value of these modalities for post-POEM monitoring is not based on good evidence; a smaller study recently suggested a limited value of post-POEM radiography [20]. We therefore retrospectively analyzed our POEM experience with respect to the possible value of fluoroscopy and endoscopy for early recognition of complications. For this purpose we compared two different time periods with and without contrast swallow. Routine CT as described by one Chinese group [21] was not part of our post-procedure work-up.

**Patients and methods**

POEM was performed under general anesthesia in 228 patients (59.6% male, mean age 45.6 ± 15.5 years) during 61 months. Details of patients, indications, and procedure are shown in Table 1; this table also includes the two groups, divided by the performance of contrast swallow after POEM in the first 114 cases, while in the second group of the subsequent 114 cases, this was omitted. Written informed consent was obtained from all patients.

Information about patient findings and clinical course during and after POEM was retrospectively analyzed from data that had been collected using a uniform approach described below. Patients included in several studies with ethics committee approval (registration numbers PV3725 and PV4133, ethical committee of the Hamburg Chamber of Physicians) [12, 22, 23] are also included here. Specific data on POEM complications have been described elsewhere [13].

**POEM performance**

The POEM procedure was then performed as described by Inoue et al. [2] Patients were admitted one day prior to the POEM procedure, to undergo upper GI endoscopy for removal of food residues from the esophagus and to rule out contraindications such as active esophagitis. Patients had no oral intake for ≥ 8 h prior to the POEM procedure. On the day of the procedure, antibiotics (metronidazole plus ciprofloxacin or cefuroxim) and double-dose proton pump inhibitors (PPIs; pantoprazole, omeprazole, or esomeprazole) were administered intravenously and this was maintained throughout the hospital stay. POEM was carried out with the patient under general anesthesia. The mouth and esophagus were rinsed with chlorhexidine. A forward-viewing upper endoscope (GIF H180J, Olympus, Hamburg, Germany) was used, with an oblique transparent distal cap (MH 588, Olympus, Hamburg, Germany). Carbon dioxide gas was used for insufflation during the procedures. An endoscopic submucosal dissection (ESD) knife (KD-640L TriangleTipKnife, Olympus, Hamburg, Germany) was used for submucosal access and dissection and to divide circular muscle fibers over a minimum length of 5 cm in the esophagus, and 2 cm onto the cardia with transmural cutting of the sphincter and a 2 cm length above and below. An electro-generator (Erbe Vio 300D, Erbe Elektromedizin, Tübingen, Germany) was used with Endocut Q mode (effect 2) to open the mucosa and various cutting and coagulation modes (e.g. spray coag effect 2, 50 W) to dissect the submucosa and divide the muscle fibers. The mucosal entry site was finally closed using standard endoscopic clips (HX-110UR EZ Clip Reusable Rotatable Clip Fixing Device and HX-610-135L Single Use Clips, Olympus, Hamburg, Germany). Patients had no oral intake for 24 h after POEM and were then allowed a liquid diet for the next 24 h. At discharge patients were given a double dose of PPIs and they were asked to stay on a soft diet for 2 weeks. In case of pain and/or nausea, pain medication and or antiemetic medication were prescribed.

**Immediate post-POEM examinations and further follow-up**

Clinical examinations were carried out on the evening of the procedure day, and thereafter once or twice per day. Laboratory tests including measures of blood picture and C-reactive
protein (CrP) were done twice during the hospital stay if not required more frequently for clinical reasons.

Upper GI endoscopy (esophagogastroduodenoscopy [EGD]) was performed in all 228 cases, a mean of 2.5 ± 0.7 days after POEM; in detail, mostly on post-procedural day 2 [44.7% (102/228)] or day 3 [42.1% (96/228)]; the remaining patients were monitored endoscopically on day 1 [6.1% (14/228)], day 4 [6.6% (15/228)], or day 5 [0.4% (1/228)].

Postoperative fluoroscopy was only performed in group 1 using a Philips EasyDiagnost fluoroscopic system in average within three days (post-procedural day 1, n = 53; day 2, n = 10; day 3, n = 41; day 4, n = 6; day 5, n = 4) using 300 mg iodine/ml water-soluble contrast media. The remaining patients underwent fluoroscopy on day 4 or 5. Fluoroscopy was not performed in two patients with major adverse events and in one patient for organizational reasons. The aim of the fluoroscopic contrast swallow was to document the number and position of the esophageal clips, to rule out clip dislocation. The amount of post-procedural free subphrenic air was documented. In addition the patient’s swallowing function was documented: timely or delayed esophageal passage was distinguished, and the presence of residual contrast material in the distal esophagus was compared with esophagographic findings in normals. Most importantly, an assessment was done for signs of perforation and for the presence of paraluminal submucosal contrast medium.

### Outcome parameters and statistical analysis

The primary outcome of this retrospective study was the ability of fluoroscopy versus endoscopy in the detection of post-POEM mucosal defects and leakages, both of the entry site clipped and the mucosa overlying the tunnel with the myotomy. Secondary outcomes were patient outcomes using only endoscopy as control (group 2) versus endoscopy plus fluoroscopy (group 1), and overall complications.

### Table 1 Patient and procedural data; with the exception of the procedure times (p = 0.002), none of the parameters were statistically significantly different between the groups (p > 0.05)

<table>
<thead>
<tr>
<th>Patient number</th>
<th>n = 228 (all cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male:female</td>
<td>67/47</td>
</tr>
<tr>
<td>Age</td>
<td>45.62 ± 15.84</td>
</tr>
<tr>
<td>Range (years)</td>
<td>18–87</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Idiopathic achalasia</td>
<td></td>
</tr>
<tr>
<td>- Type I</td>
<td>n = 17</td>
</tr>
<tr>
<td>- Type II</td>
<td>n = 74</td>
</tr>
<tr>
<td>- Type III</td>
<td>n = 16</td>
</tr>
<tr>
<td>- No recent manometrya</td>
<td>n = 0</td>
</tr>
<tr>
<td>EGI outflow obstruction</td>
<td>n = 1</td>
</tr>
<tr>
<td>&quot;Nutcracker&quot; esophagus</td>
<td>n = 2</td>
</tr>
<tr>
<td>Myotomy elongation (after Heller)</td>
<td>n = 1</td>
</tr>
<tr>
<td>Prior treatment</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>n = 60</td>
</tr>
<tr>
<td>Balloon dilation only</td>
<td>n = 40</td>
</tr>
<tr>
<td>Botox injection only</td>
<td>n = 6</td>
</tr>
<tr>
<td>Both</td>
<td>n = 8</td>
</tr>
<tr>
<td>Heller myotomy</td>
<td>n = 4</td>
</tr>
<tr>
<td>Procedure timea</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD (min)</td>
<td>91.1 ± 32.35</td>
</tr>
<tr>
<td>Range (min)</td>
<td>42–200</td>
</tr>
<tr>
<td>Myotomy lengthb</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD (cm)</td>
<td>11.77 ± 3.24</td>
</tr>
<tr>
<td>Range (cm)</td>
<td>4–23</td>
</tr>
<tr>
<td>Hospitalization</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD (days)</td>
<td>3.76 ± 0.88</td>
</tr>
</tbody>
</table>

*aClinical, endoscopic, and radiographic appearance corresponded to type I or II

| n = 70 |
| n = 118 |

b*n = 118
Data are reported as means, with 95% confidence intervals (95% CI) or standard deviation (SD) as appropriate. Continuous variables were compared using Student’s t test, and categorical data were compared using Fisher’s test. Nominal p values are reported; two-sided p values less than 0.05, were considered significant. The statistical software package R 3.0.1 was used for statistical analyses [24].

Results

POEM with general anesthesia was successfully achieved in 227 of 228 patients. Patient and procedure details are shown in Table 1 and have been previously reported in part for subgroups [12, 22, 23]. The length of the entry site was usually 3 cm in proximal–distal direction and 8–12 clips were usually required for a full and secure closure. Transmural cutting was achieved in all cases at least 2 cm above and below the LES. Clinical case examples are shown in Figs. 1 and 2.

Detection of leakages by fluoroscopy versus endoscopy

Group 1

Contrast swallow using water-soluble contrast material, that was undertaken in 114 of 114 patients in group 1, suggested leakage at the mucosal entry site in 2 patients. In one of these patients, a 10-cm-longish paraluminal contrast material cavitation with a presumed esophageal connection at the site of the implanted clips was suggested; however, there was no evidence of further leakage into the mediastinum. The defect at the entry site was confirmed by subsequent endoscopy which also showed dehiscence, and further clips were successfully placed. In the other case fluoroscopy also suggested leakage but no abnormality could be detected at endoscopy and the clinical course was uneventful. In the latter patient, it was supposed that esophageal passage of the contrast medium was delayed distally to the clipping site.

Fig. 1  A A Patient with fluoroscopic and endoscopic leakage. The bolus of contrast medium is separating at the clipping site, to pass into a right luminal passage and the pathological extraluminal passage. Furthermore post-procedural subphrenic free air can be seen. B Same case, further filling of the extraluminal cavity connecting with the clipping site. C Same case, after passage of the bolus, some contrast medium remains in the extraluminal cavity formed by the POEM procedure, with no passage from thence into the mediastinum. D Same case, endoscopic aspect confirming leakage of the mucosal entry site closure; this defect was successfully reclipped.
because of mucosal swelling combined with distal esophageal dilatation due to the chronic achalasia. Endoscopy in addition identified 2 further cases of problems with entry site closure, where clips had fallen off leading to a small amount of dehiscence. Reclipping was done in all these 3 patients. While 2 patients were discharged after endoscopic screening 2 and 3 days later, the 3rd patient, an asymptomatic young woman (31 years), received two further endoscopies with reclipping to achieve full closure.

In 5 further cases, endoscopy showed missing clips but the entry site appeared to be closed without visible leakage. These patients underwent reclipping and were discharged in the standard way.

**Group 2**

Early post-POEM endoscopy was performed in all 114 patients in group 2. Dislocation of clips was observed in 5 cases. While 3 of those patients did not show any sign of clinical (emphysema, pneumoperitoneum) or endoscopic (dehiscence, bleeding) leakage, the other 2 patients showed emphysema and pneumoperitoneum or hematoma, respectively. All patients were successfully reclipped and discharged by standard protocol. Two additional patients developed a hematoma until early post-POEM endoscopic control with neither clip dislocation nor clinical or laboratory manifestation. One case showed only a small hematoma and was discharged regularly, while the other one was observed clinically and endoscopically due to bigger hematoma. Eventually this patient was discharged a few days later after finding the hematoma dissolving. Due to clinical deterioration of a 51-year-old patient (pain, vomiting, tachycardia, and a temperature of 38.3 °C) we performed endoscopic evaluation on postoperative day 1 which revealed an ischemic defect over the third of esophageal circumference with perforation at the gastric cardia. As discussed previously (14), the lesion was not applicable for clipping. Therefore, this patient was transferred to an intensive care unit, underwent surgical

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**Fig. 2** A Another patient with presumed paraluminal passage suggested by fluoroscopy. On the right esophageal border, connected to the clipping site, a thin 3-cm-long line of contrast medium can be seen, that is possibly extraluminal. B Same case, review of the images after knowledge of the endoscopy report suggested that postprocedural mucosal swelling and chronic distal esophageal dilatation were mimicking paraluminal presence of contrast medium. C Same case, another aspect of B. D Same case, the absence of a closure defect was confirmed by endoscopic control.
treatment, recovered, and was discharged on day 13 after POEM. Nonetheless surgery included a resection of the distal two-thirds of the esophagus followed by a gastric pull-up during the same session. The patient recovered uneventfully and showed normal activity over the follow-up visits.

Detection of mucosal defects by fluoroscopy versus endoscopy

Group 1

Mucosal defects on the mucosal surface of the submucosal tunnel were seen in 8 cases. Among these, 4 patients remained hospitalized: one had a small mucosal lesion in the tubular esophagus that was clipped and was endoscopically monitored 2 days later; one patient had a 1-cm ulcer in the cardia that was endoscopically checked 1 day and 4 days later; another patient had a 2 × 1-cm fundic ulcer distal to the submucosal channel, that was checked 2 days later; and finally, one patient had a small ulcer at the gastroesophageal junction that was endoscopically monitored 4 days later. In addition, in 3 patients fibrin-covered small erosions in the distal esophagus were seen and in 1 patient a fissure of the cardia opposite the submucosal tunnel was seen; these were not treated or monitored endoscopically.

Group 2

In 16 cases mucosal lesions were observed. Of those, 5 showed ulcers without any sign of perforation. All of these lesions were seen in the area of the submucosal tunnel. Two of the patients with ulcers remained in the hospital for a longer period (7 and 12 days, respectively), on one hand due to a pale area around the ulcer, suspicious of a perfusion deficit, and on the other hand due to signs of bleeding from the ulcer. Both patients were observed clinically, received endoscopic reevaluation, and could be discharged without further complications.

Another, previously discussed 33-year-old man (14), showed, next to small mucosal erosions, signs of a hematoma underneath the mucosal surface. After developing pain, slight dyspnea, and a drop of hemoglobin level (from 15.9 to 11.5 g/dl over 48 h) during the clinical course a computed tomography was performed and revealed a hemathorax. After placing a chest drain the patient recovered and was discharged on day 18 after POEM without clinical sequelae.

Further fluoroscopic findings in group 1, without clinical consequences and not shown in the Table, were small amounts of residual gas (CO₂) in the esophageal wall (submucosal tunnel) in 1 case, and small amounts of free air below the diaphragm in 71 of 114 cases (62.3%). In 18 of these 70 cases (25.7%), free abdominal gas was noted clinically during the procedure and immediately drained percutaneously.

Comparison of gross immediate outcomes in the two groups

This is summarized in Table 2. It is evident that the overall rate of complications almost tripled between the two groups; this was however caused by a much larger rate of mucosal lesions (7 vs. 14%) which did not lead to further manifestations but were just observed, similarly to 0 versus 4 mucosal hematomas. The two much more significant major complications both occurred in the second group and became evident clinically and by endoscopy. The rate of asymptomatic clip dislocations remained the same in both groups.

Discussion

POEM as a new technique for the endoscopy therapy of idiopathic achalasia that has been established in 2010 and has aroused great interest since then. As an offspring of natural orifice transluminal surgery (NOTES), it allowed for the first time to work endoscopically outside of the esophageal lumen in a defined indication [2, 18, 19, 25]. Since randomized controlled trials are not yet available, current evidence is based on many mostly retrospective case series of variable size, summarized in no less than fourteen meta-analyses [6–9, 17–19, 25–30]. Some of them have focused on complications [17–19], and the rate of major complications is reported to be in the range of 1–3%, while minor complications vary greatly due to difficulties and inconsistencies in definition [13].

Table 2 Complications during hospital stay in both groups detected/confirmed on early post-POEM endoscopy; clip dislocation is recorded separately but cannot be defined as a complication since it did not lead to clinical sequelae (see text)

<table>
<thead>
<tr>
<th>Complication/event observed</th>
<th>Group 1 with contrast swallow (N = 114)</th>
<th>Group 2 without contrast swallow (N = 114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Mucosal lesions/ulcers</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Hemathorax</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Ischemia</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>Clip dislocation without clinical symptoms</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>
POEM can be considered as rather invasive due to the transluminal approach. Therefore, the fear of complications has been substantial especially in the initial phase of application, both during and after the procedure. Among the latter, especially leakage with serious consequences such as mediastinitis had been expected, but fortunately proved to be extremely rare. Nevertheless, this has led to—at least initially—tight post-procedure controls, including clinical and laboratory tests as well as endoscopy and radiology. In a few centers even routine CT was performed [21].

Examinations such as endoscopy and contrast swallow have been scheduled before patients are discharged, to check the integrity of the mucosa overlying the myotomy and for the robustness of the closure of the entry site. Initially, we considered both endoscopy and fluoroscopy using water-soluble contrast agent to be helpful for this purpose. We have therefore systematically performed both after each POEM procedure, and analyzed the comparative value of these tests after 114 cases in comparison to a similar number of subsequent cases without fluoroscopy which we stopped since we felt it may not be helpful.

Our results show that endoscopy alone is sufficient in detecting minor defects at the entry site as well as minor lesions of the mucosa overlying the myotomy and that most of those were missed by fluoroscopy with water-soluble contrast agent. Fluoroscopy using contrast swallow has been considered the easiest test to detect leakages after esophageal surgery. The diagnostic value of fluoroscopy with water-soluble contrast agent is however limited to major leakages. In the older radiologic literature, examinations using barium sulfate contrast agents had an increased sensitivity in the detection of esophageal perforation [31–33]. Water-soluble contrast agents, on the other hand, seem to have some advantages in the detection of pharyngeal lesions [34]. Only if clinically mandated, further tests such as thoracic CT are needed. In a study from Shanghai, routine CT revealed a high rate of minor findings with respect to air leakage (pneumomediastinum, pneumothorax, cutaneous emphysema, pleural effusion, and pneumonic infiltrates), while on the basis of clinical symptoms only a small minority of these needed interventions [21]. On the basis of our results, we think that only one simple test (endoscopy) should be performed after a potentially risky procedure such as POEM. This confirms previous experience in smaller patient numbers and without a comparative group [35].

Furthermore, it is debatable whether minor clip closure defects, and especially clip dislocations without significant dehiscence, are of clinical consequences, so that even endoscopic controls could be discussed in case of normal clinical recovery. Nevertheless, and even more so in the early phase of a new procedure with unknown complications such as POEM, we tried to detect and reclip all patients who had dislocated clips irrespective of whether a significant defect or dehiscence of the closed mucosal entry site was seen on endoscopy or not. This was, because we feared the infectious consequences of even minor leakage of saliva and fluid/food into the mediastinum. Local endoscopic interventions may then be too late. Similarly, all mucosal perforations occurring during laparoscopic Heller myotomy are carefully closed and oversewn. Final conclusions whether to skip all controls, endoscopic and radiologic, in patients without symptoms or worsening laboratory abnormalities, are not possible, but a cautious approach still seems to be advisable to us. Naturally, we cannot prove that these cases of small dehiscence would have led to clinically apparent consequences if left alone, since all cases were reclipped.

Another aspect of our analysis is that procedure times did not shorten during the first 228 cases when comparing the two groups with 114 cases each; in contrast, as an effect of the learning curve, shorter times would be expected. On the other hand, in a previous study focusing on complications we could also show that the rate of minor adverse events was increasing rather than decreasing over the course of time [13]. This could be due to expanded indications and inclusion of more difficult and risky cases, but we can only speculate about causative factors.

In summary, our results show that endoscopy with the option of direct intervention is sufficient for early post-POEM monitoring, and radiologic methods (fluoroscopy and/or CT) should be reserved for cases with clinical suspicion of leakage and/or infection. Further studies will focus on overall effectiveness in comparison with balloon dilation and Heller myotomy—such randomized multicenter trials are under way—as well as on procedural and technical details.

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Author Contributions Jan-Friso Nast und Yuki Werner were responsible for designing and conducting the analysis, data collection, and performance of study manometry. Christoph Berliner reviewed the radiologic images and contributed to data analysis and writing the paper. Daniel von Renteln, Guido Schachs chal, Ulrike Denzer, and Stefan Groth carried out POEM procedures and/or monitoring examinations and contributed to writing the paper. Tanja Noder was responsible for patient inclusion, data collection, and monitoring. Harald Ittrich and Gerhard Adam reviewed the manuscript and contributed to the Discussion section. Jan Kersten was responsible for the statistical analysis. Thomas Rösch was responsible for designing and conducting the study, data collection, data analysis, and writing and revising the manuscript. All authors revised and approved the final manuscript. The authors would also like to thank H. Inoue and H. Minami for training and helping to introduce the POEM procedure of this study.
Compliance with ethical standards

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