Preoperative endoscopic pyloric balloon dilatation decreases the rate of delayed gastric emptying after Ivor–Lewis esophagectomy

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SUMMARY. Delayed gastric emptying (DGE) after Ivor–Lewis esophagectomy occurs postoperatively in up to 50% of the patients. This pyloric dysfunction can lead to severe secondary complications postoperatively such as early aspiration, pneumonia or may even have an impact on anastomotic healing and therefore leakage. Early detection of DGE is essential to prevent further complications. The common treatment postoperatively is endoscopic pyloric balloon dilatation (EPBD) after symptoms already occurred. In our work, we analyzed patients who received a preoperative EPBD during the routine restaging endoscopy and compared those patients to a control group to analyze if preoperative EPBD may prevent postoperative DGE and secondary additional complications. We performed a single-center retrospective analysis of 115 patients who received an Ivor–Lewis esophagectomy by the same surgeon between June 2015 and October 2017. Out of these 115 patients, 91 (79.1%) patients received EPBD preoperatively during the staging/restaging endoscopy (PDG, pyloric dilatation group). In 24 (20.9%) patients, preoperative EPBD was not performed due to stenotic esophageal tumors or logistic reasons (NDG, non-pyloric dilatation group). Data of the PDG and NDG group were compared regarding the rate of postoperative DGE as well as DGE and EPBD related complications. In total, 21 (18.3%) patients developed pyloric dysfunction requiring a total of 27 EPBD during follow-up. There were 12 (13.2%) patients in the PDG and 9 (37.5%) patients in the NDG (p = 0.014), respectively. DGE-related complications such as anastomotic leaks (p = 0.466), pulmonary complications (p = 0.466) and longer median hospital stay (p = 0.685) were more frequent in the NDG group; however this difference did not reach statistical significance. The success rate for postoperative EPBD with 20-mm balloons was lower (58.5%) compared to the usage of 30-mm balloons (93.3%). All pre- and postoperative EPBD were performed without any complications. Preoperative EPBD is feasible, safe and can be combined with restating endoscopy. It seems that preoperative EPBD reduces the incidence of DGE and can prevent the need for early postoperative endoscopic interventions. Our recommendation is therefore to perform an EPBD preoperatively when possible to reduce postoperative complications to a minimum. For postoperative EPBD, we recommend the use of the 30-mm balloon due to lower redilatation rates.

KEY WORDS: gastric emptying, gastric pull-up, Ivor–Lewis, minimally invasive esophagectomy, pneumatic dilation.

INTRODUCTION

The treatment of choice for the most stages of esophageal carcinoma is a subtotal esophagectomy with gastric conduit reconstruction with either intrathoracic (Ivor-Lewis procedure) or cervical anastomosis (McKeown procedure) (1, 2). In the past years, perioperative morbidity and mortality decreased significantly because of improvement of surgical strategies and perioperative management as well as better patient selection and treatment of patients preferably in high-volume centers (3, 4).
Although in recent years morbidity rates after Ivor-Lewis procedure could be reduced remarkably, postoperative delayed gastric emptying (DGE) due to pyloric dysfunction still occurs in about 10–50% of the patients (5, 6). This complication is a result of the truncal vagotomy performed during the resection and the elevation of the stomach from the positively pressured abdomen to the negatively pressured thorax (7, 8). DGE is supposed to lead to higher rates of postoperative complications and prolonged hospitalization (9). DGE can be treated by postoperative EPBD safely and effectively; however, the patients are not treated until symptoms and often even associated secondary complications of DGE are present (10). Thus, in view of the increased morbidity related to DGE, prevention seems to be favored over treatment of DGE.

Intraoperative surgical pyloric drainage procedure (pyloromyotomy, pyloroplasty or botox injection) are effective in lowering the risk of DGE (11) and consecutive risk of aspiration pneumonia (12,13) but bear an increased risk of reflux, dumping syndrome and even surgical complications (14, 15). So far, there is only one study by Swanson et al. including very small number of 25 patients investigating the use of preoperative EPBD to prevent DGE. This study is showing promising results with only one patient required re-intervention; however the data are limited for valid conclusions (16).

To assess the value of preoperative EPBD to prevent DGE, we compared data of patients with and without EPBD preoperatively.

MATERIAL AND METHODS

Patients

All patients who underwent surgery for esophageal cancer were recorded in our prospective institutional esophageal surgery database. Between June 2015 and October 2017, a total of 115 consecutive patients underwent subtotal esophagectomy with gastric conduit reconstruction and a standardized intrathoracic anastomosis (Ivor–Lewis procedure) for esophageal cancer. Operations were performed in all patients from the same specialized surgeon (17–19). Intraoperatively, a pyloric drainage procedure was never performed.

Preoperative endoscopy

All patients underwent a staging and in case of neoadjuvant therapy also restaging endoscopy under intravenous sedation few days (0–6 days) prior to surgery. Propofol (Fresenius® Kabi) was used for sedation during this endoscopy. In 91 (79.1%) patients, a preoperative EPBD was performed (PDG, pyloric dilatation group). In 24 (20.9%) patients, preoperative EPBD was not performed because of stenotic esophageal tumors or logistic reasons (NDG, non-pyloric dilatation group). In the PDG, the pylorus was dilated for 2 minutes using a 20-mm controlled radial expansion (CRE) esophageal balloon dilator (Boston Scientific, Ireland). The dilatation was performed through the scope (TTS) under endoscopic vision by inflating water in the CRE balloon dilator with a maximum inflation pressure of 608 kPa.

Postoperative care

The gastric tube was removed prior immediate extubation after surgery and the patients were transferred to intensive care unit (ICU) breathing spontaneously. We did not perform a routine contrast swallow study postoperatively. In case of a postoperative regular course, we started a liquid diet on postoperative day (POD) 4.

Postoperative delayed gastric emptying

DGE was diagnosed clinically. The definition was early satiety, dysphagia, nausea and vomiting after intake of liquid or solid food. This definition is consistent with a systematic review, although there is still a lack of consensus in the definition of DGE (12). In case of these symptoms, the early feeding process was stopped and a postoperative endoscopy was initiated after 24 hours of fasting. In case of a pyloric dysfunction, EPBD was carried out with a 20-mm CRE esophageal balloon dilator (Boston Scientific, Ireland) or with a 30-mm RIGIFLEX achalasia balloon dilator (Boston Scientific, Ireland). If the pylorus was wide or if the symptoms persisted after EPBD a contrast swallow or a CT scan with oral contrast was initiated to exclude another diagnosis.

Study endpoints

Data of the PDG and NDG group were compared regarding the rate of postoperative DGE as well as the rate of DGE- and EPBD-related complications.

Statistical analysis

All statistical tests were performed using the Software Package SPSS for Windows, Version 23.0 (Chicago, IL). The two sided Fisher exact probability test was used for the bivariate analyses. Multivariate analyses were performed using logistic regression models. The level of significance was set at $p < 0.05$. 

RESULTS

Patient characteristics

In total, 115 consecutive patients (82.6% male) with a median age of 62 years (range: 26–82 years)
underwent esophagectomy with gastric conduit reconstruction. Of these 115 patients, 75 patients (65.2\%) had adenocarcinoma, 36 patients (31.3\%) had squamous cell carcinoma and 4 patients (3.4\%) had other neoplasms of the esophagus. Out of all patients, 52 patients (45.2\%) had undergone neoadjuvant radiochemotherapy, 34 patients (29.6\%) had undergone neoadjuvant chemotherapy and 29 patients (25.2\%) had no pretreatment. Of the 115 patients, 2 patients (1.7\%) had open surgery, 35 patients (30.4\%) received hybrid esophagectomy, 42 patients (36.5\%) underwent minimally invasive esophagectomy (MIE) and 36 patients (31.3\%) were treated with a robot-assisted MIE (RAMIE). Median follow-up time was 16 months (range: 4–32 months). The majority of patients were classified with high perioperative risk defined by the ASA classification (ASA III, 50.4\%). The median number of resected lymph nodes was 23 (range: 7–84) and did not differ significantly between the two groups (\(p = 0.899\)). The surgical margins of 111 patients (96.5\%) were negative for cancer without showing statistical significance (\(p = 1.00\)) between the groups. 30-day and 90-day mortality were 1 (0.9\%) and 2 (1.7\%) respectively (Tables 1, 2).

### Preoperative EPBD

In 91 (79.1\%) patients, the pylorus was dilated preoperatively (PDG) whereas 24 (20.9\%) patients did not receive a preoperative dilatation of the pylorus (NDG). The median time between preoperative EPBD and surgery was 1 day (range: 0–6 days). In most patients, the dilatation was performed one or two days prior to surgery (71.3\%). There were no EPBD-related complications.

### Postoperative DGE

In total, 21 (18.3\%) patients developed pyloric dysfunction requiring EPBD during follow-up. There were 12 (13.2\%) patients in the PDG and 9 (37.5\%) patients in the NDG (\(p = 0.014\), respectively. The median time between surgery and postoperative EPBD was 14 days (range: 7–118 days). Within the first 14 POD after Ivor-Lewis procedure, only 5 (5.5\%) PDG patients but 6 (25\%) NDG patients underwent re-endoscopy and EPBD due to pyloric dysfunction (\(p = 0.01\)). Multivariate regression analysis revealed omission of preoperative EPBD as a significant independent risk factor for DGE (\(p = 0.005\)) (Table 3).
DGE-related complications are listed in Table 4. There was a trend toward less frequent incidence of DGE-related complications such as anastomotic leaks ($p = 0.466$), pulmonary complications ($p = 0.466$) and a shorter median hospital stay ($p = 0.685$) in the PDG; however this difference did not reach statistical significance.

### DISCUSSION

In this study we found that preoperative EPBD is feasible and safe. Moreover, preoperative EPBD can reduce the incidence of DGE significantly and thus the need for early postoperative endoscopy. These are the most striking results of our study.

Despite continuous improvement in surgical technique, DGE remains a frequent complication after esophagectomy due to several reasons e.g. as a result of the truncal vagotomy (7, 8). Over the time, the myenteric plexus becomes the center of gastric motility and the denervated stomach recovers (20). In 2014 Akkerman et al. demonstrated in a systematic review several other risk factors for the functional disorder. Gastric conduit reconstruction had a lower rate of DGE compared to the whole stomach reconstruction (6). The retrosternal reconstruction for cervical anastomosis had a lower rate of reflux but DGE was similar compared to mediastinal reconstruction. Similar DGE results were seen comparing intrathoracic and cervical anastomosis. In literature, the reported rates of DGE vary between 10 and 50% depending on the definition of DGE, time of transition to a normal diet, different surgeons or surgical techniques (in particular whether intraoperatively a pyloric drainage procedure has been performed or not) and a lack of clinical follow-up (21, 22). DGE is supposed to lead to higher rates of postoperative complications and prolonged hospitalization (9). This finding was confirmed in our study with a clear although not significant tendency to an increased number of complications and a prolonged hospital stay.

As seen in previous studies by Lanuti et al. and also in our series DGE can be treated by postoperative EPBD safely and effectively (10). In this study, all patients with DGE symptoms postoperatively were

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**Table 3. Multivariate analyses**

<table>
<thead>
<tr>
<th></th>
<th>DGE</th>
<th>Odds ratio</th>
<th>DGE until POD 14</th>
<th>Odds ratio</th>
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</thead>
<tbody>
<tr>
<td>sex</td>
<td>0.423 (ns)</td>
<td>0.724 (ns)</td>
<td></td>
<td></td>
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<tr>
<td>age</td>
<td>0.952 (ns)</td>
<td>0.779 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA risk class</td>
<td>0.853 (ns)</td>
<td>0.889 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pathology</td>
<td>0.652 (ns)</td>
<td>0.623 (ns)</td>
<td></td>
<td></td>
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<tr>
<td>induction therapy</td>
<td>0.605 (ns)</td>
<td>0.706 (ns)</td>
<td></td>
<td></td>
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<tr>
<td>surgery</td>
<td>0.243 (ns)</td>
<td>0.355 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>lymph nodes</td>
<td>0.292 (ns)</td>
<td>0.884 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R0 resection</td>
<td>0.424 (ns)</td>
<td>0.999 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mortality</td>
<td>0.999 (ns)</td>
<td>0.999 (ns)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>preoperative EPBD</td>
<td>0.005</td>
<td>6.610</td>
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**Table 4. Preoperative EPBD**

<table>
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<tr>
<th>Preoperative EPBD, days prior surgery</th>
<th>n, (%)</th>
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<tbody>
<tr>
<td>0</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>1</td>
<td>74 (64.3)</td>
</tr>
<tr>
<td>2</td>
<td>8 (7.0)</td>
</tr>
<tr>
<td>3</td>
<td>5 (4.3)</td>
</tr>
<tr>
<td>5</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>6</td>
<td>1 (0.9)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Length of hospital stay, median (range)</th>
<th>PDG (91)</th>
<th>NDG (24)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 (9-115)</td>
<td>13 (9-91)</td>
<td>0.685 (ns)</td>
<td></td>
</tr>
</tbody>
</table>

| Length of ICU stay, median (range)    | 2 (1-115) | 3 (2-84) | 0.641 (ns) |

| Pneumonia, n (%)                      | 9 (9.9) | 4 (16.7) | 0.466 (ns) |

| Anastomotic leak, n (%)               | 9 (9.9) | 4 (16.7) | 0.466 (ns) |

| DGE, n (%)                            | 12 (13.2) | 9 (37.5) | 0.014 |

| DGE until POD 14, n (%)               | 5 (5.5) | 6 (25) | 0.010 |
treated successfully with EPBD requiring one to three dilatations. Unfortunately it is not possible to identify patients who will likely develop a postoperative DGE. These patients are not treated until symptoms and often even associated secondary complications occur (10). This opens two possibilities, either prevention or treatment after development of symptoms.

In many centers, an intraoperative pyloric drainage procedure is the standard of care but results regarding this procedure remained controversial (6). Urschel et al. demonstrated in a meta-analysis that pyloric drainage procedures reduce DGE but have no effect on pulmonary complications or overall survival (13). In 2015, Arya et al. showed in a systematic review that pyloric drainage procedures were associated with a trend toward reduced rates of anastomotic leaks, pulmonary complications and DGE (12). In contrast, Palmes et al. showed that pyloric drainage procedures increase the risk of bile reflux and esophagitis (14). There are also data that show an increased risk of dumping syndrome and even surgical complications (23). For the same reason, we do not perform a pyloric drainage procedure.

An alternative to the intraoperative pyloric drainage procedure is the EPBD (24). In 2012, Swanson et al. performed EPBD preoperatively in 25 patients and showed that only one patient (4%) required re-EPBD postoperatively (16). The limitations of the study were the different types of esophagectomies and a small number of patients. This study is the first showing that patients undergoing EPBD preoperatively had a significantly lower incidence of DGE compared to a control group, thus the need for early postoperative endoscopic interventions was significantly reduced (5.5% until POD 14, p = 0.01). In case of symptoms of DGE, we did not try a conservative therapy in the early phase of recovery because of the risk of aspiration. We stopped the feeding process and an endoscopy was initiated. There is a lack of consensus in the definition of DGE. However in our department, we have uniform criteria for our patients. In case of a zig/zag shape of the conduit, we would not dilate the pylorus, and in addition we would not see a benefit after EPBD. The advantage of this study is the standardized procedure and the reduction of above-mentioned risk factors for the functional disorder. All investigated 115 patients in this study were operated by the same surgeon using the same resection and reconstruction principle (Ivor–Lewis esophagectomy). The abdominal part

was performed minimally invasive (laparoscopic or robotic) without an intraoperative pyloric drainage procedure. Comparing the preoperative with the intraoperative treatment, the presented preoperative EPBD during re-endoscopy seems quite uncomplicated compared to the invasive intraoperative pyloric drainages procedure.

Maus et al. demonstrated that the use of a 30-mm balloon postoperatively is safe and has a lower rate of redilatation compared to the 20-mm balloon (25). In this study, we could confirm the superiority of the 30-mm balloon for postoperative EPBD in terms of postoperative DGE. However a preoperative EPBD is not feasible using the available 30-mm RIGI-FLEX achalasia balloon dilator due to the distance to the pylorus. In a postoperative setting, after the esophageal resection and gastric conduit reconstruction, the distance is shorter and a 30-mm balloon can be used.

The most obvious disadvantage of this study is the retrospective analysis of data and the fact that it is not a randomized controlled trial. Thus, there is a clear risk for some selection bias, i.e. more advanced (stenosing) tumors in the NDG group. Certainly, a controlled randomized study would be desirable. However, the achieved data clearly points out the potential use of EPBD in preventing DGE.

**CONCLUSION**

Preoperative EPBD is both feasible and safe. It can be performed during the restaging endoscopy without requiring of an additional intervention. It reduces early postoperative interventions as well as the occurrence of DGE. Therefore we recommend the preoperative EPBD during restaging endoscopy when possible. For postoperative EPBD, we recommend the use of the 30-mm balloon due to lower redilatation rates.

**References**

6 Diseases of the Esophagus


