

# Complication rates of direct puncture and pull-through techniques for percutaneous endoscopic gastrostomy: Results from a large multicenter cohort



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## ABSTRACT

**Background and study aims** Two different techniques for percutaneous endoscopic gastrostomy (PEG) have been developed: classical pull-through and direct puncture techniques. This study compared the complication rate for both techniques in a large retrospective patient cohort.

**Patients and methods** Clinical data from patients who received a PEG in four high-volume centers for endoscopy were included retrospectively between January 2016 and December 2018. Patient characteristics and complication rates were correlated in univariate and multivariate analyses.

**Results** Data from 1014 patients undergoing a PEG insertion by the pull-through technique were compared to 183 patients for whom the direct puncture technique was used. The direct puncture technique was associated with a 50% reduction in minor and 85.7% reduction in major complications when compared to the pull-through technique. Multivariate analysis of these data revealed an odds ratio of 0.067 (0.02–0.226;  $P < 0.001$ ) for major complications in the direct puncture group.

**Conclusions** Compared to the pull-through technique, the direct puncture technique resulted in a significant reduction in complications. Despite the retrospective design of this study, these results suggest that the direct puncture technique may be preferable to improve patient safety.

## Introduction

In 1979, percutaneous endoscopic gastrostomy (PEG) was described by Gauderer et al as a new technique for performing gastrostomy without laparotomy [1]. The authors introduced

the pull-through technique for PEG. Here, a thread is placed percutaneously into the stomach and the feeding tube is pulled by this thread through the patient's mouth into the stomach and through the abdominal wall. The pull-through technique has become the standard procedure for PEG over the years.

The complication rate for this technique varies between 4.9% and 23.8% in interventions documented in the literature [2–4].

Besides pull-through, the direct puncture technique was reported about in 2007 by Toyama et al. [5], and has been applied in recent years. This technique uses a specially designed sewing needle to fix stomach and abdominal wall. After implementation of the percutaneous gastropexy, a trocar with an overlying peel-away sheath is introduced percutaneously under endoscopic control into the stomach, and after removing the trocar, the feeding tube is placed through the sheath. This technique has become the standard method in cases in which anatomical barriers related to malignant diseases such as head and neck cancer hinder the placement of a feeding tube through the esophagus.

Five trials (three prospective and two retrospective) demonstrated fewer complications with application of the direct puncture technique, especially with respect to a lower rate of local infections compared to application of the pull-through technique in 408 patients [6–10]. In 2011, different results were reported by van Dyck et al [11], who published a retrospective analysis of 57 patients, identifying the direct puncture technique to be associated with a significantly higher complication rate (11/24, 48%) when compared to the pull-through technique (4/33, 12%,  $P < 0.05$ ). Teich et al. confirmed these data in a prospective randomized trial with 120 patients (per protocol treatment) with an early complication rate of 33 serious adverse events in 58 patients in the direct puncture technique group versus 14 of 62 patients in the pull-through technique group ( $P = 0.001$ ) [4]. This thorough compilation of the complication rates with the pull-through and direct puncture techniques returned contradictory results.

Despite these contradictory results with low-quality evidence, the European Society of Gastrointestinal Endoscopy (ESGE) recommends the pull-through technique as the standard method for PEG placement, and the direct puncture technique only in cases in which pull-through is contraindicated [12].

To increase the evidence of superiority for one of these procedures, we retrospectively analyzed risk of complications for the pull-through and direct puncture techniques in our cohort of 1201 patients. The aim of this study was to estimate and compare interventional risk for both techniques, independent of possible confounders such as age, underlying disease, and indication for PEG.

## Patients and methods

### Study design and data collection

Clinical data from patients who had undergone a PEG procedure in four high volume centers for endoscopy were collected retrospectively between January 2016 and December 2018.

Data including gender, age, body mass index, underlying disease, leading indication, PEG technique, complications, and follow-up information for 60 days were retrieved from the patient management software of each center. The Institutional Ethics Review Board of the Charité – Universitätsmedizin Berlin, Germany (EA4/036/18) approved this study.

### PEG procedure

PEG procedures were based on the recommendations of the ESGE Guidelines [12].

Written informed consent for the PEG procedure was obtained from all patients at least 24 hours prior to the intervention. Only patients without clinical and serological signs of an acute infection (no leukocytosis and no C-reactive protein level more than 10 times above the norm) were eligible for PEG intervention. Patients fasted overnight. Periinterventional antibiotic prophylaxis was administered 30 minutes prior to the intervention. Patients were placed supine and were sedated with propofol and midazolam. Oxygen was applied with a nasal cannula or, if applicable, with a tracheostomy tube. During the entire procedure, heart rate, blood pressure, and oxygenation monitoring was performed following the standard sedation guidelines [13].

An esophagogastroduodenoscopy was performed to exclude any contraindications for PEG. Subsequently the stomach was insufflated with CO<sub>2</sub> for maximal stomach wall extension and, after disinfection of the abdominal wall, the site for PEG placement was chosen by gastroscopic transillumination. This area was infiltrated with lidocaine as a local anesthetic and a needle (20G) was introduced percutaneously into the stomach.

### Pull-through technique

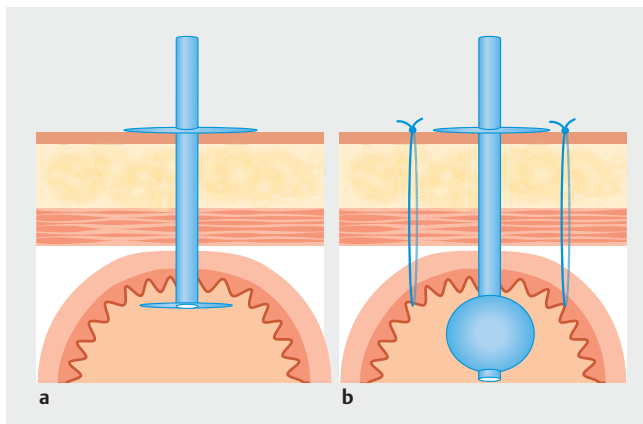
For the pull-through technique, a thread was placed into the stomach via the percutaneous needle. The thread was grabbed with endoscopic forceps and pulled out of the patient's mouth. The thread was fixed to the PEG device and the PEG tube was introduced through the mouth into the stomach by pulling the thread. The final position of the tube was reached when the internal retention disk of the tube touched the stomach wall. The internal retention disk and external fixation plate were tightened firmly for 24 hours. This process causes the stomach and abdominal wall to adhere (► Fig. 1a) [13].

### Direct puncture technique

For the direct puncture technique, the stomach and abdominal wall were fixed with the aid of a gastropexy device (Gastropexie Device II, Fresenius-Kabi Deutschland GmbH, Bad Homburg, Germany). The sutures were placed in three to four locations with a distance of approximately 2 cm around the identified PEG insertion site (► Fig. 1b). After skin incision, the trocar with an overlying peel-away sheath was inserted through the skin incision into the stomach under direct endoscopic visualization. In the next step, the metal trocar was removed, and the feeding tube was inserted through the leaving peel-away sheath in situ. After the intragastric fixation balloon was filled with water, the sheath was removed (► Fig. 1b). Gastropexy sutures were removed 2 to 3 weeks after intervention [5].

### Monitoring of complications and mortality

All patients who received a PEG were followed up by a specialized nursing team and corresponding complications were documented in the patient management software. Postinterventional complication and mortality rates were monitored for a minimum period of 60 days after intervention. Major compli-



► **Fig. 1** Schema for **a** classical pull-through technique and **b** direct puncture technique.

cations were considered when potentially life-threatening events occurred whereas minor complications were all other unwanted postinterventional events. Intervention-related mortality was defined as death caused by the PEG intervention (all cases were caused by peritonitis after PEG intervention).

### Statistical analysis

Quantitative values are expressed as mean and range, and categorical values with absolute and relative frequencies (count of events and percent). The 60-day complication probability was evaluated in the first 60 days after the intervention using Kaplan-Meier plots. The  $\chi^2$ -test was used for comparison of frequencies. Multivariate comparison of frequencies was analyzed by binary logistic regression analysis.  $P < 0.05$  was considered as statistically significant. IBM SPSS Version 21 (Ehningen, Germany) was used for statistical analysis.

► **Table 1** Patient characteristics and subgroup analysis of pull-through technique and the direct puncture technique.

	All		PEG technique				P
	Total		Pull-through		Direct puncture		
	n	(%)	n	(%)	n	(%)	
Gender							0.236
▪ Female	439	(36.6)	365	(35.9)	74	(40.4)	
▪ Male	762	(63.4)	653	(64.1)	109	(59.6)	
Age group							0.725
▪ <65 years	513	(42.7)	437	(42.9)	76	(41.5)	
▪ ≥65 years	688	(57.3)	581	(57.1)	107	(58.5)	
Body mass index (kg/m <sup>2</sup> )							<b>0.001</b>
▪ <18.5	117	(9.7)	90	(8.8)	27	(14.8)	
▪ 18.5 – 24.9	411	(34.2)	334	(32.8)	77	(42.1)	
▪ >25	420	(35.0)	367	(36.1)	53	(29.0)	
▪ unspecified	253	(21.1)	227	(22.3)	26	(14.2)	
Underlying disease							<b>&lt;0.001</b>
▪ Malignant	640	(53.3)	518	(50.9)	112	(64.7)	
▪ Neurologic	497	(41.4)	445	(43.7)	52	(30.1)	
▪ Others	64	(5.3)	55	(5.4)	9	(5.2)	
Leading indication							<b>&lt;0.001</b>
▪ Neuro motoric dysfunction	570	(47.5)	510	(50.1)	60	(32.8)	
▪ Palliative	187	(15.6)	141	(13.9)	46	(25.1)	
▪ Before radiation	427	(35.6)	364	(35.8)	63	(34.4)	
▪ Parkinson therapy	17	(1.4)	3	(0.3)	14	(7.7)	
PEG reinsertion							<b>&lt;0.001</b>
▪ No	1065	(88.7)	948	(93.1)	117	(63.9)	
▪ Yes	136	(11.3)	70	(6.9)	66	(36.1)	

PEG, percutaneous endoscopic gastrostomy.  
Significance calculated by  $\chi^2$ -test.

► **Table 2** Major and minor complications in the analyzed patient cohort and correlation with the employed PEG techniques.

	All		PEG technique				P
	Total		Pull-through		Direct puncture		
	n	(%)	n	(%)	n	(%)	
<b>Major complication</b>							
▪ All	117	(9.8)	114	(11.2)	3	(1.6)	<0.001
▪ Severe wound infection	61	(5.1)	61	(6.0)	0	(0.0)	<0.001
▪ Acute abdomen	49	(4.1)	47	(4.6)	2	(1.1)	0.026
▪ Peritonitis	67	(5.6)	65	(6.4)	2	(1.1)	0.004
▪ Subcutaneous abscess	28	(2.3)	28	(2.8)	0	(0.0)	0.023
▪ Pneumoperitoneum	43	(3.6)	43	(4.2)	0	(0.0)	0.005
▪ Ileus	9	(0.8)	8	(0.8)	1	(0.5)	0.727
▪ Requiring mechanical ventilation	27	(2.3)	26	(2.6)	1	(0.5)	0.091
▪ Major bleeding	7	(0.6)	7	(0.7)	0	(0.0)	0.260
▪ Dislocation requiring surgery	74	(6.2)	74	(7.3)	3	(1.6)	0.006
▪ Dislocation not requiring surgery	20	(1.7)	20	(2.0)	0	(0.0)	0.055
<b>Minor complication</b>							
▪ All	279	(23.3)	256	(25.2)	23	(12.6)	<0.001
▪ Increased inflammation parameter	174	(14.5)	158	(15.6)	16	(8.7)	0.016
▪ Any diagnostic procedure necessary	250	(20.9)	228	(22.5)	22	(12.0)	0.001
▪ Intervention necessary	95	(7.9)	84	(8.3)	11	(6.0)	0.295
▪ Pain	194	(16.2)	178	(17.6)	16	(8.7)	0.003
▪ Local bleeding	34	(2.8)	31	(3.1)	3	(1.6)	0.288
▪ Local wound infection	147	(12.3)	132	(13.0)	14	(7.7)	0.067
▪ Leakage	100	(8.4)	95	(9.4)	5	(2.7)	0.003
▪ Intestinal discomfort	113	(9.4)	102	(10.1)	11	(6.0)	0.085
▪ Nausea	59	(4.9)	53	(5.2)	6	(3.3)	0.262
▪ Antibiotic therapy required	148	(12.4)	133	(13.1)	15	(8.2)	0.063
▪ Parenteral nutrition required	50	(4.2)	49	(4.8)	1	(0.5)	0.008
<b>Death within 60 days after intervention</b>							
▪ All	122	(10.9)	91	(8.9)	31	(16.9)	0.001
▪ PEG-related	8	(0.7)	7	(0.7)	1	(0.5)	0.829

PEG, percutaneous endoscopic gastrostomy.  
Significance calculated by X<sup>2</sup>-test.

## Results

### Patients

Data from 1201 patients were retrieved for this study (► **Table 1**). The median age was 65.6 years with a range of 18 to 103 years. Of the patients, 36.6% (n=439) were women. Six-hundred-forty patients (53.3%) suffered from a malignant disease, 497 (41.4%) from a neurologic disorder, and 64 patients

from other disorders including disability after resuscitation, long-term ventilation or polytrauma.

In 570 cases (47.5%), the indication for a PEG procedure was neuromotor dysfunction such as recurrent aspiration, dysphagia, or reduced consciousness. In 187 cases (15.6%), it was for palliation (gastric outlet obstruction, cachexia), and in 427 cases (35.6%), it was part of prophylactic maintenance of enteral nutrition in patients with head and neck tumors during radiation therapy. Seventeen patients (1.4%) received a PEG as

► **Table 3** Subgroup analysis of pull-through and direct puncture technique-related mortality within 60 days after intervention in respect to patient characteristics.

	Intervention-related 60-day mortality								
	All			Pull-through			Direct puncture		
	n	(%)	P	n	(%)	P	n	(%)	P
Gender			0.126			0.049			0.409
▪ Female	5	(1.1)		5	(1.4)		0	(0.0)	
▪ Male	3	(0.4)		2	(0.3)		1	(0.9)	
Age group			0.246			0.446			0.234
▪ <65 years	5	(1.0)		4	(0.9)		1	(1.3)	
▪ ≥65 years	3	(0.4)		3	(0.5)		0	(0.0)	
Body mass index (kg/m <sup>2</sup> )			0.085			0.028			0.481
▪ <18.5	0	(0.0)		0	(0.0)		0	(0.0)	
▪ 18.5–24.9	6	(1.5)		6	(1.8)		0	(0.0)	
▪ >18.5	2	(0.5)		1	(0.3)		1	(1.9)	
▪ unspecified	0	(0.0)		0	(0.0)		0	(0.0)	
Underlying disease			0.41			0.024			0.778
▪ Malignant	4	(0.6)		3	(0.6)		1	(0.8)	
▪ Neurologic	2	(0.4)		2	(0.4)		0	(0.0)	
▪ Others	2	(3.1)		2	(3.6)		0	(0.0)	
Leading indication			0.841			0.979			0.392
▪ Neuromotor dysfunction	4	(0.7)		4	(0.8)		0	(0.0)	
▪ Palliative	2	(1.1)		1	(0.7)		1	(2.2)	
▪ Before radiation	2	(0.5)		2	(0.5)		0	(0.0)	
▪ Parkinson therapy	0	(0.0)		0	(0.0)		0	(0.0)	
PEG reinsertion			0.916			0.437			0.451
▪ No	7	(0.7)		6	(0.6)		1	(0.9)	
▪ Yes	1	(0.7)		1	(1.4)		0	(0.0)	
All	8	(0.7)		7	(0.7)		1	(0.5)	

PEG, percutaneous endoscopic gastrostomy.  
Significance calculated by X<sup>2</sup>-test.

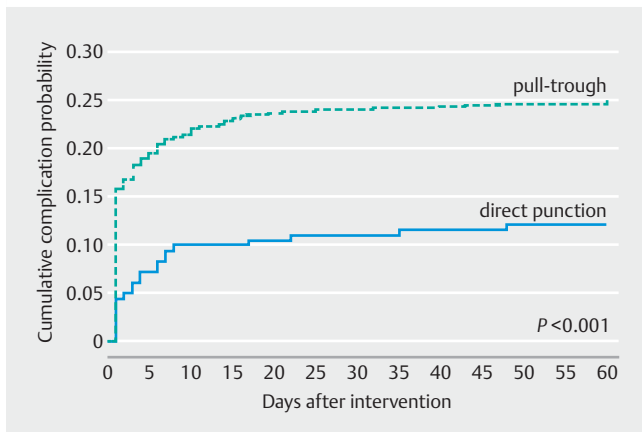
part of Duodopa therapy for their Parkinson's disease with enteral application of levodopa/carbidopa gel.

In 136 cases (11.3%), patients had a PEG previously and PEG reinsertion was necessary. The main reason for that was recurrence of a head and neck cancer.

Direct puncture was performed in 183 cases (15.3%) of the interventions and was significantly more common in underweight and normal weight patients ( $P=0.001$ ), in patients with malignant diseases ( $P<0.001$ ), individuals with an indication for palliation or Duodopa therapy ( $P<0.001$ ), and in cases in which a PEG reinsertion was necessary (► **Table 1**).

## Complications

Major complications occurred in 117 of 1201 cases (9.8%). The leading causes were severe wound infection (5.1%), peritonitis (5.6%), and PEG dislocation (6.2%) (► **Table 2**). Minor complications occurred in 279 of 1201 cases (23.3%) and required an additional diagnostic procedure in 250 cases (20.9%). Minor complications were, in detail: increased inflammation parameter (14.5%), local wound infections (12.3%), requirement for antibiotics (12.4%), and pain (16.2%) (► **Table 2**). Comparisons of the two techniques revealed a significant reduction in the major complication rate by 85.7% in the direct puncture group (direct puncture 1.6%, pull-through 11.2%;  $P<0.001$ ). The mi-



► **Fig. 2** Cumulative probability for complications in the first 60 days after intervention depending on pull-through technique (n = 1018) and direct puncture technique (n = 183). Significance calculated by log-rank test.

nor complication rate also was reduced by 50% in the direct puncture group when compared to the pull-through group (direct puncture technique 12.6%, pull-through technique 25.2%;  $P < 0.001$ ) (► **Table 2**). In particular, the rate of infection-related complications, acute abdomen, peritonitis, pneumoperitoneum, pain, and PEG leakage were significantly reduced by using the direct puncture technique.

Overall 60-day mortality was significantly higher in the direct puncture group (16.9%) than in the pull-through group (8.9%);  $P < 0.001$ ). Detailed examination of 60-day mortality showed a significantly higher number of cases with malignant diseases and palliative PEG indications in the direct puncture group (► **Table 3**). Therefore, analysis of the intervention-

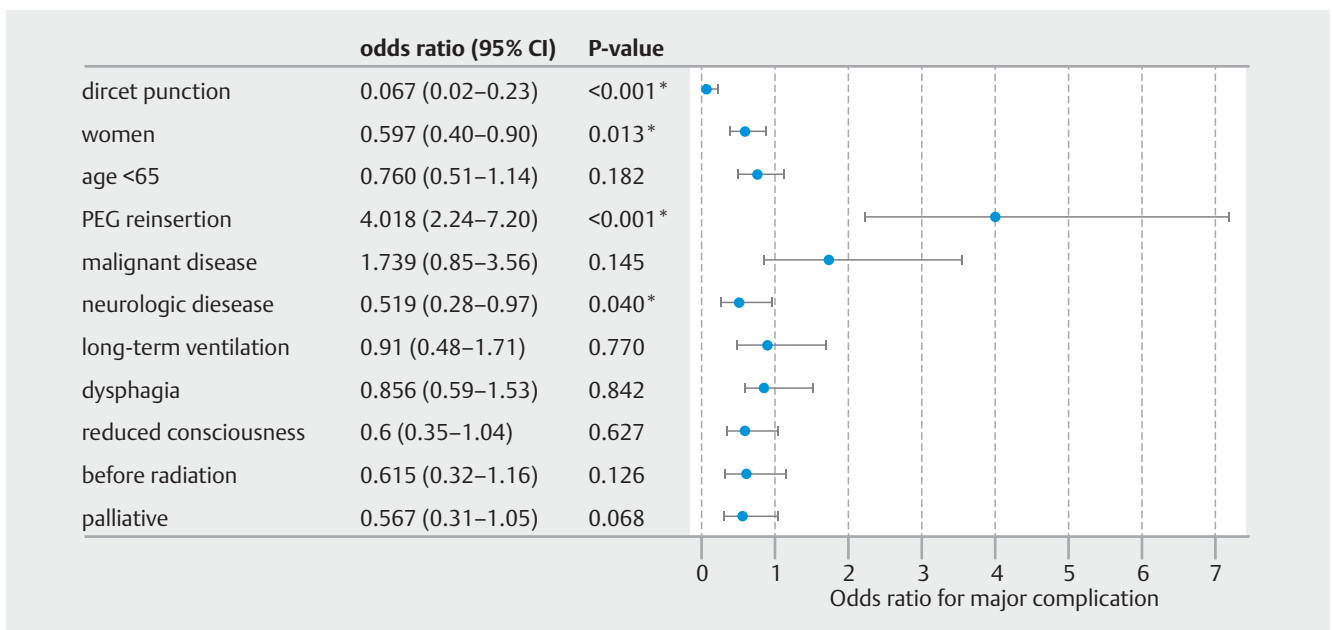
specific mortality could not confirm this difference (pull-through technique 0.7% [n = 7] vs. direct puncture technique 0.5% [n = 1];  $P = 0.829$ , ► **Table 2**). A subgroup analysis of intervention-related 60-day mortality revealed significantly higher mortality in women, normal weight patients, and patients with malignant disease in the pull-through technique group, whereas the direct puncture technique group showed no significant differences in the subgroup analysis (► **Table 3**). Despite their statistical significance, the subgroup effects have no practical relevance due to the low number of intervention-related deaths (pull-through technique n = 7, direct puncture technique n = 1).

Most complications occurred in the first 24 hours after the intervention. In this time window, the complication rate was significantly increased in the pull-through technique group. After 24 hours, the complication rate was comparable for the two techniques (► **Fig. 2**).

To identify independent risk factors for major complications, a multivariate binary logistic regression analysis was performed. The analysis identified the direct puncture technique as the strongest protective factor (odds ratio [OR] 0.067; 95% CI 0.02–0.226;  $P < 0.001$ ). PEG reinsertion procedure was identified as the highest risk for complication (OR 4.018 [95% CI: 2.24–7.20]  $P < 0.001$ ). A lower risk for complications was seen in women (OR 0.597 [95% CI: 0.40–0.90]  $P = 0.013$ ) and patients with neurological disease (OR 0.519 [95% CI: 0.28–0.97]  $P = 0.040$ ) (► **Fig. 3**).

## Discussion

This retrospective multicenter analysis aimed to compare the complication rates of PEG procedures by comparing two techniques: classical pull-through and direct puncture. Our data



► **Fig. 3** Multivariate binary logistic regression analysis for major complication risk in PEG procedures. Significance calculated by log-rank test (\*level of significance reached).

provide evidence indicating a clear advantage of the direct puncture technique with a complication rate of 1.6% compared to the pull-through technique with 11.2% ( $P < 0.001$ ) within the first 60 days after intervention. Multivariate analysis revealed an OR of 0.067 for direct puncture, resulting in a 14.9-fold increase in major complications by using the pull-through technique.

Subgroup analysis indicated that for the direct puncture technique, the decrease in complications was driven by a reduction in infections (severe wound infection, peritonitis, and subcutaneous abscess) as well as complications related to insufficient adherence of stomach and abdominal wall (peritonitis, acute abdomen, pneumoperitoneum, and dislocation requiring surgery). The reduction in infectious complications documented here for use of the direct puncture technique was previously reported in five of seven studies comparing the two techniques [4–9,11]. Most authors suggested that the increased infection rate in the pull-through technique group was mediated by the spread of bacteria from the oropharyngeal area [6–10]. This occurs during the pull-through of the PEG tube through the mouth and esophagus, which is not required with the direct puncture technique.

To our knowledge, this is the first time that a significant reduction in acute abdomen by using direct puncture has been described. This may be due to the low incidence of these events (4.1%), which requires a larger study population. Most of the complications associated with both techniques occurred within the first 24 hours following the intervention. The main advantage of direct puncture was the reduction in these early complications.

When evaluating these data, it must be considered that the major complication rate in the group that underwent direct puncture was so low that a subgroup analysis could only be evaluated for the pull-through technique group (► **Table 3**).

Two previous publications identified an increased rate of tube dislocation when using direct puncture technique as a potential disadvantage [4,11]. This may be due to the balloon technique. Remarkably, this was not detected within the 60-day observation period in our study.

Inherent in retrospective studies, patient stratification was not possible. The gastrostomy technique was selected by the individual physician and was dependent on the respective indication of the underlying disease. Patient characteristics were not for BMI, leading indications, underlying diseases, and rate of PEG reinsertion. The direct puncture group included more patients receiving palliation, who had an almost doubled 60-day overall mortality rate. This higher mortality and morbidity in the direct puncture group was also observed in two other retrospective analyses: A higher overall mortality rate (direct puncture technique 8%, pull-through technique 0%) was found in a study population not balanced for World Health Organization performance status (direct puncture technique = 2, pull-through technique = 1) [11], and Tucker et al. reported a higher percentage of patients receiving palliation in the direct puncture technique group (direct puncture technique 82.7%, pull-through technique 12.0%). Mortality was not analyzed in this study [8]. Heterogeneity of patients in our cohort was unfavor-

able for the outcome of the direct puncture technique, but despite this imbalance, the minor and major complication rates were significantly reduced in patients with poor prognosis who underwent direct puncture.

Because of the retrospective design of this study, it must be considered that it is possible that not all post-intervention complications could be monitored after the patients were discharged from the hospital. Given the close follow-up care of our specialized care teams, there will only be a few cases here. This confounder will also affect both groups equally.

## Conclusions

PEG is one of the interventions with the highest complication rates in interventional endoscopy, but it is still considered a safe procedure. This analysis of our large patient population identified a 90% reduction in major complication rate associated with use of the direct puncture technique. Despite the retrospective design of this study, the data suggest the superiority of direct puncture and provide justification for the initiation of larger, prospective randomized multicenter trials. Based on the results we have presented, current practice of PEG should be carefully reconsidered, pending the availability of results from controlled studies.

## Competing interests

The authors declare that they have no conflict of interest.

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#### CORRECTION

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