Hybrid percutaneous endoscopic gastrostomy (Hybrid PEG) improves patient safety by combining pull-through technique with gastropexy

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Authors

Tobias Horst Kinzel[1], Viktoria Reich[1], Leonie Schuhmacher[1], Christian Bojarski[1], Andreas Adler[2], Wilfried Veltzke-Schlieker[2], Christian Jürgensen[2], Frank Tacke[2], Britta Siegmund[1], Juliane Buchkremer[1], Federica Branchi[‡1], Christoph Treese[‡1]

Institutions

1 Medizinische Klinik für Gastroenterologie, Infektiologie und Rheumatologie, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany

2 Medizinische Klinik mit Schwerpunkt Hepatologie und Gastroenterologie, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany

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Georg Thieme Verlag KG, Oswald-Hesse-Straße 50, 70469 Stuttgart, Germany

Corresponding author

Dr. Christoph Treese, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Medizinische Klinik für Gastroenterologie, Infektiologie und Rheumatologie, Berlin, Germany
christoph.treese@charite.de

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ABSTRACT

Background and study aims The direct puncture technique has been associated with a better safety profile compared with the classical pull-through technique for insertion of a percutaneous endoscopic gastrostomy (PEG). In this study, the safety of the hybrid PEG technique, combining gastropexy with the pull-through technique, was analyzed in a large retrospective patient cohort.

Patients and methods Clinical data from patients undergoing PEG insertion in a high-volume center for endoscopy were included retrospectively between January 2016 and December 2021. Patient characteristics and complication rates were correlated in univariate and multivariate analyses.

Results Data from 351 patients undergoing PEG insertion with the hybrid PEG technique were compared with 145 procedures with the direct puncture technique and 1073 procedures with the pull-through technique. In the group where gastropexy was performed (hybrid PEG and direct puncture), we could not find any significant differences in frequency of major and minor complications. Comparing the pull-through technique with the gastropexy group, we detected a five-fold higher major complication rate and a doubled minor complication rate for the pull-through technique. Multivariate analysis confirmed the protective role of gastropexy, with an odds ratio of 0.166 (0.084–0.329; $P < 0.001$) for major complications.

Conclusions Hybrid PEG and direct puncture are equally safe PEG insertion techniques, with significantly better safety profiles than the pull-through technique. Despite the retrospective design of the study, these results suggest preferential use of hybrid PEG due to handling.

‡ These authors contributed equally.

Introduction

Insertion of percutaneous endoscopic gastrostomy (PEG) is a well-established routine procedure in endoscopy. Despite its routine use, the complication rate for the procedure varies considerably in the literature, with estimates ranging from 4.9 to 23.8% [1, 2, 3]. In essence, two distinct PEG techniques are typically employed: the pull-through method, which is the predominant approach, and the direct puncture technique following gastropexy. The European Society of Gastrointestinal Endoscopy (ESGE) currently recommends the classic pull-through technique as the standard method for PEG insertion, with the direct puncture technique only being employed in cases where pull-through is contraindicated [4]. In a recent large retrospective cohort study, we were able to provide evidence indicating that the direct puncture technique is more effective than the classic pull-through technique. This was demonstrated by a 90% reduction in frequency of major complications and a 50% reduction in frequency of minor complications, respectively. Multivariate analysis in this study revealed a 14.9-fold increase in major complications when the classic pull-through technique was employed [5]. Notably, the primary reduction in complications was observed within the first 24 hours. The findings indicate that the enhanced safety of the direct puncture is primarily attributable to the gastropexy performed prior to tube insertion. In addition, the pull-through technique offers advantages in terms of handling (reduced risk of tube dislocation) and costs (reduced material usage, no need for frequent tube replacement) [3, 6]. In light of these data, we have introduced the hybrid PEG procedure as a routine technique in our daily practice. The hybrid PEG procedure involves performance of a gastropexy and subsequent insertion of a pull-through PEG tube (first described by Grund et al. (▶ **Fig. 1**) [7]).

The objective of this study was to analyze the safety profile of the different techniques for PEG insertion. A retrospective analysis was performed to assess risk of complications associated with hybrid PEG and to compare it with recently published data on classic pull-through and the direct puncture techniques [5].

Material and methods

Study design and data collection

Clinical data from patients who underwent a PEG procedure in two high-volume centers for endoscopy were collected retrospectively between January 2016 and October 2021.

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 the center. The Institutional Ethical Review Board of the Charité - Universitätsmedizin Berlin, Germany (EA4/036/18) approved this study

PEG procedure

PEG procedures were conducted according to recommendations in the ESGE Guidelines [4].

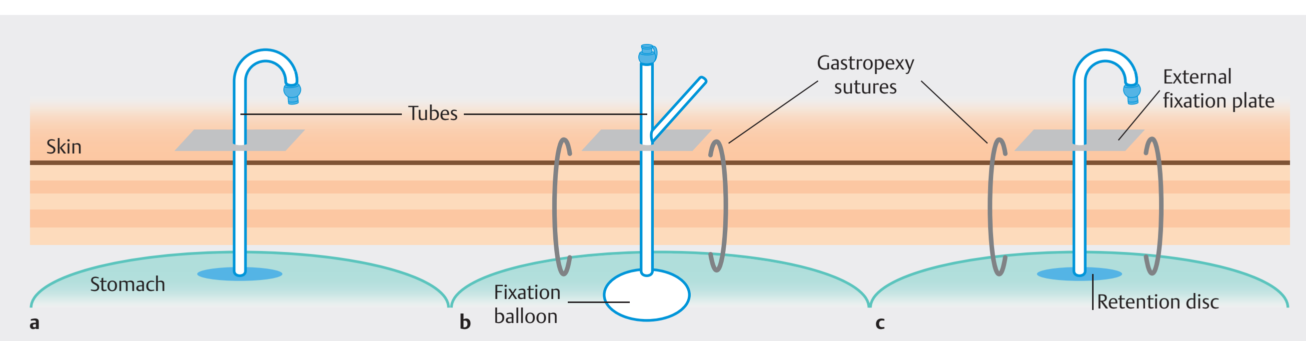
General preparation

Written informed consent for the PEG procedure was obtained in all patients at least 24 hours before intervention. Patients fasted overnight. Periinterventional antibiotic prophylaxis was administered 30 minutes before intervention. Patients were placed supine and were sedated with propofol and/or midazolam. Oxygen was applied by a nasal cannula or, if applicable, by tracheostomy tube. During the entire procedure, heart rate, blood pressure, and oxygenation monitoring were performed following the standard sedation guidelines [8].

An esophageal-gastro-duodenoscopy was performed to exclude any contraindications for PEG. Subsequently, the stomach was insufflated with CO_2 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 (20 G) was introduced percutaneously into the stomach.

Classic pull-through technique

In the classic pull-through technique, a thread was inserted into the stomach through a puncture cannula. The thread was grasped by endoscopic forceps and extracted orally. The thread was subsequently fixed to a standard PEG tube (usually 15F,



▶ **Fig. 1** Scheme of PEG insertion with a the classical pull-through technique, b the direct puncture technique, and c the hybrid PEG technique. PEG, percutaneous endoscopy gastrostomy.

with exceptions including decompression-PEG for palliative reasons, where a 20F tube was inserted), which was introduced into the stomach through the oral route by pulling the thread. Final tube position was achieved when the internal retention disc of the tube made contact with the stomach wall. The internal retention disc and external fixation plate were then tightened firmly for a period of 24 hours. This process causes the stomach and abdominal wall to adhere (▶ **Fig. 1a**) [5]

Direct puncture technique

For the direct puncture technique, a gastropexy was performed, whereby the stomach and abdominal wall were fixed with a gastropexy device (Gastropexie Device II, Fresenius-Kabi Deutschland GmbH, Bad Homburg, Germany). The sutures were placed in three to four locations within approximately 2 cm around the identified PEG insertion site (▶ **Fig. 1b**). After skin incision, a metal trocar (geared to tube size, usually 15F or 20F.) with an overlying peel-away sheath was inserted through the skin incision into the stomach under direct endoscopic visualization. In the next step, the trocar was removed, and a balloon-feeding tube was inserted through the peel-away sheath. After the intragastric fixation balloon was filled with water, the sheath was removed (▶ **Fig. 1b**). Gastropexy sutures were removed 10 to 14 days after intervention [9].

Hybrid PEG technique

For hybrid PEG, the first step was performance of a gastropexy for fixation of the stomach to the abdominal wall with the gastropexy device, as described above. Subsequently, a puncture cannula was inserted, and a standard PEG tube was placed by pull-through via thread through the mouth into the stomach as described above (▶ **Fig. 1c**).

Monitoring of complications and mortality

Postintervention complication and mortality rates were monitored for a minimum period of 60 days after the intervention. Major complications were considered when potentially life-threatening events occurred whereas minor complications were all other unwanted postintervention events. Intervention-related mortality was defined as death caused by 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 X^2-test was used for comparison of frequencies. Multivariate comparison of frequencies was analyzed by binary logistic regression analysis. $P < 0.05$ was considered statistically significant. IBM SPSS Version 21 (Ehningen, Germany) was used for statistical analysis.

Results

A total of 1,569 patients were included in this study (▶ **Table 1**). Median age was 65.4 years, with a range from 18 to 102 years. The study population consisted of 546 women, representing 34.8% of the total. Eight-hundred-forty-nine patients (54.1%) had a malignant disease, 621 (39.6%) had a neurologic disorder, and 99 patients had other disorders, including disability resulting from resuscitation, long-term ventilation, or polytrauma. In 732 cases (46.7%), the indication for a PEG procedure was a neuro-motoric dysfunction, such as recurrent aspiration, dysphagia, or reduced consciousness; in 240 cases (15.3%), it was a palliative reason (gastric outlet obstruction, cachexia); and in 570 cases (36.3%), it was part of prophylactic maintenance of enteral nutrition in patients with head and neck tumors during radiation therapy. Twenty-seven patients (1.7%) received a PEG to allow enteral application of levodopa/carbidopa gel as a treatment for Parkinson disease. In 68 cases (4.3%), patients had a PEG before, and a reinsertion was necessary, mainly due to recurrence of head and neck cancer.

The direct puncture technique was employed in 145 cases (9.3%), the hybrid PEG technique in 351 cases (22.4%), and the classic pull-through technique in 1073 cases (68.4%). In total, 496 PEG insertions (31.6%) were performed with the aid of gastropexy.

In light of findings from previous studies indicating a superior safety profile for gastropexy-aided PEG [5], we conducted a comparative analysis of the three PEG insertion techniques. In addition, we evaluated the gastropexy-aided PEG insertions collectively (both direct puncture and hybrid PEG) in comparison with classic pull-through.

A comparison of clinical and demographic data between the classic pull-through group and the hybrid PEG group revealed significant differences in age (65.2% of patients in the hybrid group were aged < 65 years, compared with 56.8% in the classic pull-through group; $P = 0.005$), body mass index (BMI > 25 kg/m^2 in 36.2% of patients in the hybrid PEG group, compared with 23.4% in the classic pull-through group; $P < 0.001$), and leading indication (the hybrid PEG group had a lower proportion of patients who were palliative and a higher proportion of patients who had undergone radiation therapy; $P < 0.001$) (Supplementary Table 1). A comparison of patient characteristics between the direct puncture group and the hybrid PEG group revealed a notable imbalance with regard to underlying diseases and primary indication for the procedure. The direct puncture group exhibited a higher prevalence of malignancy and indications related to cancer, including palliative care, radiation therapy, and PEG reinsertion ($P < 0.001$) (**Supplementary Table 2**).

The comparison between the classic pull-through group and the two gastropexy-aided groups revealed differences in patient characteristics. The gastropexy group exhibited a higher prevalence of malignant diseases ($P = 0.014$) and a greater number of indications related to cancer, including palliative ($P < 0.001$) and pre-radiation ($P < 0.001$) cases, compared with the pull-through group (▶ **Table 1**).

▶ **Table 1** Patient characteristics and subgroup analysis of classic pull-through and gastropexy-aided techniques (hybrid and direct puncture).

	All		**PEG technique**				
	Total		**Pull-through**		**Hybrid and direct puncture**		***P***
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	
Gender							0.327
Female	546	(34.8)	382	(35.6)	164	(33.1)	
Male	1023	(65.2)	691	(64.4)	332	(66.9)	
Age group							0.090
< 65 years	656	(41.8)	464	(43.2)	192	(38.7)	
≥ 65 years	913	(58.2)	609	(56.8)	304	(61.3)	
Body mass index (kg/m2)							< 0.001
< 18.5	139	(8.9)	95	(8,9)	44	(8.9)	
18.5–24.9	598	(38.1)	403	(37.6)	195	(39.3)	
≥ 25	410	(26.1)	251	(23.4)	159	(32.1)	
unspecified	421	(26.8)	323	(30.1)	98	(19.8)	
Underlying disease							0.014
Malignant	849	(54.1)	557	(51.9)	292	(58.9)	
Neurologic	621	(39.6)	451	(42.0)	170	(34.3)	
Others	99	(6.3)	65	(6.1)	34	(6.9)	
Leading indication							< 0.001
Neuromotor dysfunction	732	(46.7)	534	(49.8)	198	(39.9)	
Cancer - before radiation	570	(36.3)	364	(33.9)	206	(41.5)	
Palliative	240	(15.3)	173	(16.1)	67	(13.5)	
Parkinson therapy	27	(1.7)	2	(0.2)	25	(5.0)	
PEG reinsertion							0.046
No	1501	(95.7)	1019	(95.0)	482	(97.2)	
Yes	68	(4.3)	54	(5.0)	14	(2.8)	0.327

Significance calculated by X2-test. PEG, percutaneous endoscopy gastrostomy.

Complications

A total of 115 of 1,569 cases (7.4%) exhibited major complications, including wound healing issues (3.4%), peritonitis (4.0%), and acute abdomen (2.9%). Minor complications were observed in 306 cases (19.6%) and required performance of an additional diagnostic procedure in 250 cases (16.0%). These minor complications included relevant pain (12.8%), elevated inflammation markers (11.3%), and wound infections (9.1%) (▶ **Table 2**).

Major complications

A comparison of the classic pull-through technique with the two gastropexy techniques (hybrid PEG and direct puncture) revealed a reduced occurrence of major complications in the gastropexy group (2.0% vs 9.8%; *P* < 0.001). Incidence of major complications was significantly reduced, with the exception of major bleeding events and ileus (▶ **Table 2**). The same differences were observed when comparing the classic pull-through and the hybrid PEG technique (*P* < 0.001) (**Supplementary Table 3**). When analyzed separately, the two gastropexy-aided techniques did not differ with respect to major complication rates (2.1% direct puncture technique vs 2.0% hybrid PEG; *P* = 0.957) (**Supplementary Table 4**).

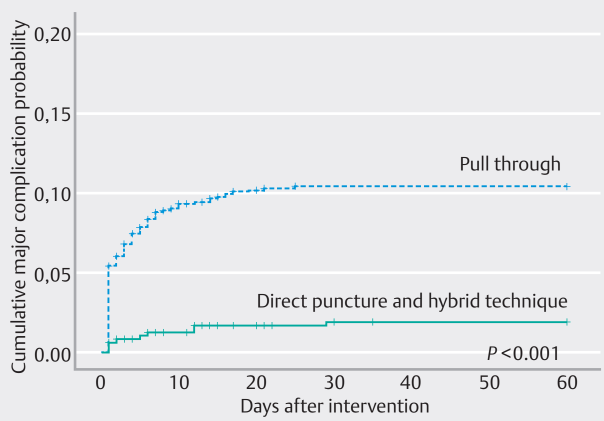
Minor complications

The rate of minor complications was also reduced in the gastropexy-aided group (hybrid PEG and direct puncture) as compared with the pull-through group (11.1% vs 23.5%; *P* < 0.001). Detailed analysis identified a risk reduction for the gastropexy-aided PEG insertions for every category of minor complications (▶ **Table 2**). These results were confirmed in the separate com-

▶ **Table 2** Major and minor complications in the analyzed patient cohort and correlation with the employed PEG techniques (pull-through technique and puncture technique with gastropexy [hybrid and direct puncture technique]).

	All		**PEG technique**				
	Total		**Pull-through**		**Hybrid and direct puncture**		***P***
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	
All complications							< 0.001
No complication	1255	(80.2)	817	(76.5)	438	(88.3)	
Any complication	309	(19.8)	251	(23.5)	58	(11.7)	
Complications within 24 hours	177	(11.3)	159	(14.9)	18	(3.6)	< 0.001
Major complications							
All	**115**	**(7.4)**	**105**	**(9.8)**	**10**	**(2.0)**	**< 0.001**
Wound healing complication	53	(3.4)	52	(4.9)	1	(0.2)	< 0.001
Subcutaneous abscess	24	(1.5)	23	(2.2)	1	(0.2)	0.003
Peritonitis	63	(4.0)	60	(5.6)	3	(0.6)	< 0.001
Pneumoperitoneum	47	(3.0)	42	(3.9)	5	(1.0)	0.002
Acute abdomen	45	(2.9)	43	(4.0)	2	(0.4)	< 0.001
Ileus	9	(0.6)	8	(0.7)	1	(0.2)	0.183
Major bleeding	6	(0.4)	5	(0.5)	1	(0.2)	0.427
Dislocation							
▪ not requiring surgery	66	(4.2)	64	(6.0)	2	(0.4)	< 0.001
▪ requiring surgery	19	(1.2)	17	(1.6)	2	(0.4)	0.046
Intensive care required	27	(1.7)	24	(2.2)	3	(0.6)	0.020
Mechanical ventilation required	24	(1.5)	23	(2.2)	1	(0.2)	0.003
Minor complications							
All	**306**	**(19.6)**	**251**	**(23.5)**	**55**	**(11.1)**	**< 0.001**
Increased inflammatory markers	176	(11.3)	155	(14.5)	21	(4.2)	< 0.001
Wound infection	142	(9.1)	126	(11.8)	16	(3.2)	< 0.001
▪ Antibiotic therapy required	153	(9.8)	130	(12.2)	23	(4.6)	< 0.001
Pain	200	(12.8)	173	(16.2)	27	(5.4)	< 0.001
▪ Pain medication required	181	(11.6)	163	(15.3)	18	(3.6)	< 0.001
Minor bleeding	33	(2.1)	29	(2.7)	4	(0.8)	0.015
Intestinal discomfort	115	(7.4)	99	(9.3)	16	(3.2)	< 0.001
Nausea	60	(3.8)	48	(4.5)	12	(2.4)	0.047
Leakage	92	(5.9)	87	(8.1)	5		< 0.001
Any diagnostic procedure required	250	(16.0)	222	(20.8)	28	(5.6)	< 0.001
Radiological diagnostic required	131	(8.4)	113	(10.6)	18	(3.6)	< 0.001
Intervention required	87	(5.6)	74	(6.9)	13	(2.6)	0.001
Parenteral nutrition required	50	(3.2)	44	(4.1)	6	(1.2)	0.002
Death within 60 days after intervention							
All	129	(8.2)	89	(8.3)	40	(8.77)	0.877
PEG-related	9	(0.6)	7	(0.7)	2	(0.543)	0.543

Significance calculated by X2-test. PEG, percutaneous endoscopy gastrostomy.



▶ **Fig. 2** Cumulative probability of complications in the first 60 days after intervention depending on pull-through technique (n = 1073) vs the direct puncture and hybrid technique (n = 496). Significance calculated by log-rank test (Mantel-Cox). PEG, percutaneous endoscopy gastrostomy.

parison between hybrid PEG and classic pull-through technique (**Supplementary Table 3**).

A comparison of the two gastropexy-aided techniques revealed that hybrid PEG was superior to direct puncture with regard to post-procedure increase in inflammation parameters. Specifically, hybrid PEG demonstrated a 2.3% increase in inflammation parameters, whereas direct puncture exhibited a 9.0% increase ($P = 0.001$). Hybrid PEG was associated with a significantly lower incidence of wound infections (1.4% vs. 7.6%; $P < 0.001$) and a reduced need for pain medication (2.6% vs. 6.3%; $P = 0.047$) compared with direct puncture (**Supplementary Table 4**).

The majority of complications occurred during the first 24 hours following the intervention. The complication rate was significantly higher with the classic pull-through technique than with both gastropexy-aided techniques during that period (14.9% vs 3.6%, $P < 0.001$, ▶ **Table 2** and **Supplementary Table 5**). However, after 24 hours, the complication rate was comparable for all techniques (▶ **Fig. 2**). These results were corroborated by a comparison of the classic pull-through technique and hybrid PEG (**Supplementary Fig. 1**). No significant differences were observed in the complication rate within the first 24 hours between the two gastropexy-aided techniques (hybrid PEG and direct puncture) (**Supplementary Fig. 2**).

Mortality

Overall 60-day mortality rate was 7.7%, with PEG-related mortality accounting for 0.6% of the total. There were no significant differences in PEG-related mortality among the three different PEG insertion techniques, nor between the classic pull-through technique and gastropexy-aided techniques (▶ **Table 2** and **Supplementary Table 6**).

Multivariate analysis

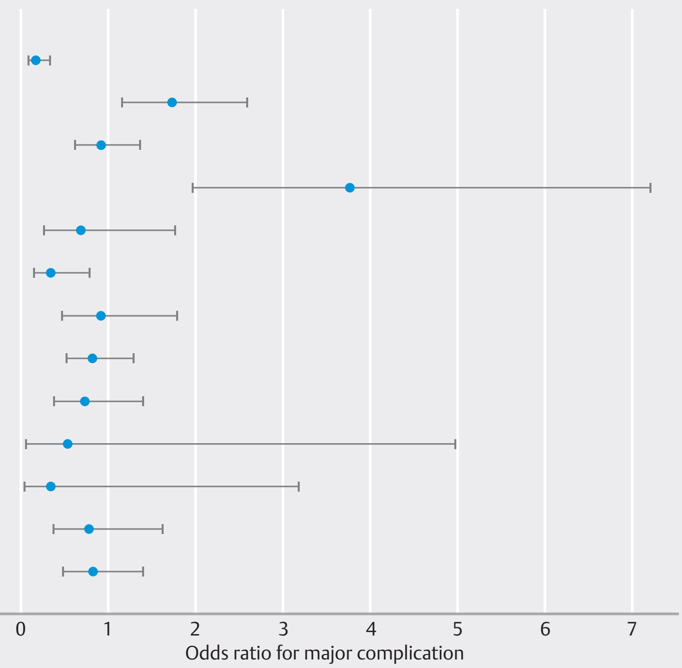
To identify independent risk factors for major complications, a multivariate binary logistic regression analysis was performed. The analysis identified performance of a gastropexy as the strongest protective factor (OR 0.166; 95% confidence interval [CI] 0.084–0.329; $P < 0.001$). A PEG reinsertion procedure was identified as the procedure with the highest risk for complications (OR 3.760 [95% CI 1.966–7.192] $P < 0.001$). Detailed analysis showed that there were significantly more patients with underlying malignancies in the reinsertion group (69.1% reinsertion vs 53.4% first insertion ($P = 0.024$). Because reinsertions are often associated with cancer recurrence, it is likely that these patients have increased morbidity (**Supplementary Table 7**). This also explains the significantly higher incidence of wound healing complications, infections and subcutaneous abscesses. Furthermore, a higher risk of complications was also observed in women (OR 1.727; 95% CI 1.152–2.589; $P = 0.008$). With regard to underlying diseases, patients with neurological diseases exhibited a significantly lower risk of major complications (OR 0.338 [95% CI: 0.146–0.782]; $P = 0.011$) (▶ **Fig. 3**). Similar results were observed when the analysis was performed comparing only the hybrid PEG group and the classic pull-through group (**Supplementary Fig. 3**).

Discussion

As previously documented, direct puncture has been linked to a notable decline in PEG-related complications when compared with conventional pull-through [5]. Despite its favorable safety profile, direct puncture presents certain challenges. First, it has a higher risk of tube dislocation over time [3]. Technically, direct puncture is more demanding than classic pull-through not only due to performance of a gastropexy, but also due to use of a relatively large trocar instead of a small cannula for puncture. In addition, the instruction for the balloon tubes utilized in the direct puncture PEG procedure recommends a first replacement after 30 days and thereafter every 90 days, which results in frequent physician contact and higher costs [10]. Hybrid PEG, which involves combining gastropexy with pull-through placement of the PEG tube, was developed to address technical challenges associated with direct puncture while maintaining its safety profile [1].

This retrospective analysis represents the first attempt to assess the safety profile of hybrid PEG in a large patient cohort. Our data indicate a clear safety advantage for gastropexy-aided PEG insertions with a complication rate of 2.0% as compared with 9.8% ($P < 0.001$) for classic pull-through, as previously reported [5]. Conversely, no discernible difference in terms of safety was observed between gastropexy performed as part of direct puncture PEG or as part of hybrid PEG. Findings from this study indicate that the primary safety benefit of gastropexy is reduction in major complications in the initial days following intervention. Multivariate analysis revealed an odds ratio (OR) of 0.166 (95% CI 0.084–0.329; $P < 0.001$) for use of gastropexy, corresponding to a six-fold reduction in major complications

	Odds ratio (95 % CI)	*P*-Value
Direct punction and hybrid	0.166 (0.084 – 0.329)	<0.001
Women	1.727 (1.152 – 2.589)	0.008*
Age 65+	0.913 (0.611 – 1.364)	0.658
PEG reinsertion	3.760 (1.966 – 7.192)	<0.001*
Malignant disease	0.686 (0.268 – 1.760)	0.433
Neurolgic disease	0.338 (0.146 – 0.782)	0.011*
Long-term ventilation	0.916 (0.473 – 1.774)	0.796
Dysphagia	0.820 (0.520 – 1.292)	0.392
Reduced consciousness	0.732 (0.385 – 1.391)	0.341
Before radiation	0.532 (0.057 – 4.967)	0.580
Palliative	0.336 (0.036 – 3.176)	0.342
BMI <18.5	0.777 (0.373 – 1.619)	0.500
BMI >25	0.820 (0.482 – 1.396)	0.465



▶ **Fig. 3** Multivariant binary logistic regression analysis for major complication risk. Significance calculated by Wald test. *Level of significance reached. Model with pull-through vs both gastropexy techniques. BMI, body mass index; PEG, percutaneous endoscopy gastrostomy.

when gastropexy-aided techniques are employed in place of classic pull-through.

Subgroup analyses indicate that occurrence of major infectious complications, as well as complications secondary to insufficient adherence of the stomach and abdominal wall (e. g., peritonitis, acute abdomen, and dislocation requiring surgery), was reduced by 79.6% using gastropexy-aided PEG insertion ($P < 0.001$). This phenomenon has been previously described by other groups using direct puncture [3, 9, 10, 11, 12, 13, 14]. It was postulated that the elevated infection rate observed in the classic pull-through group was a consequence of bacteria being transported from the oropharyngeal area during the pull-through procedure [6, 10, 12, 13, 14]. However, our data indicate that this contamination route does not significantly contribute to development of complications. Conversely, performance of a gastropexy is the primary protective factor against complications. The protective effect of gastropexy can be observed with both direct puncture and hybrid PEG. The complication rate is lower in both groups separately when compared with classic pull-through. In addition, comparison of the two gastropexy-aided techniques reveals that the occurrence of minor infectious complications in the group of hybrid PEGs is significantly lower than in the direct puncture group (**Supplementary Table 4**). This may be attributed to the fact that hybrid PEG is less demanding and invasive.

The main limitation of this study is its retrospective design. Choice of PEG insertion technique was made individually by the physicians, based on several factors including underlying disease, indication, BMI, and anatomy. These confounders were included in the multivariate model, where gastropexy was the strongest independent protective factor for major complications.

PEG insertion constitutes a routine component of endoscopic practice. In the majority of cases, patients presenting with this condition have a complex clinical history, and the reported complication rate (between 4.9% and 23.8%) is notably higher than that observed for other routine interventions [1, 2, 3]. In our study, we demonstrated a significant reduction in incidence of major complications by 79.6% and of minor complications by 52.8% associated with use of gastropexy-aided techniques in comparison with classic pull-through. Our findings suggest that the hybrid PEG technique may be the most favorable in terms of safety, feasibility, and cost-effectiveness. Further studies, particularly prospective multicenter trials, are encouraged to corroborate our data on the superiority of gastropexy, particularly of the hybrid PEG technique, and to modify the currently recommended clinical standards for PEG insertion.

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Conflict of Interest

Tobias Kinzel, Leonie Schuhmacher, Victoria Reich, Christian Bojarski, Andreas Adler, Winfried Veltzke-Schlieker, Frank Tacke, Britta Siegmund, and Juliane Buchkremer have no conflicts of interest or financial ties to disclose that relevant for this manuscript.

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