

Prospective evaluation of malignant cell seeding after percutaneous endoscopic gastrostomy in patients with oropharyngeal/esophageal cancers

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Background and study aims: Insertion of a percutaneous endoscopic gastrostomy (PEG) is standard care for many patients with oropharyngeal (ENT) and esophageal malignancies in order to ensure enteral feeding. The current pull-through insertion technique involves direct contact with the tumor and case reports have demonstrated the presence of metastases at insertion sites. The aim of the current study was to prospectively evaluate the risk of malignant cell seeding and the development of abdominal wall metastases after PEG placement.

Patients and methods: A total of 50 consecutive patients with ENT/esophageal tumors were included. After PEG placement (40 pull-through technique, 10 direct insertion), brush cytology was taken from the PEG tubing and the transcutaneous incision site. A second cytological assessment was performed after a follow-up period of 3–6 months.

Results: In total, 26 patients with ENT cancer, 13 with esophageal cancer, and one with esophageal

infiltration of lung cancer underwent pull-through PEG placement with no immediate complications. Cytology following brushing of tubing and incision sites demonstrated malignant cells in 9/40 cases (22.5%). Correlation analyses revealed a higher rate of malignant seeding in older patients and in those with higher tumor stages. At follow-up, cytology was undertaken in 32/40 patients who had undergone pull-through PEG placement. Malignant cells were present in three on cytology, resulting in a metastatic seeding rate of 9.4%.

Conclusion: This study showed that malignant cells were present in 22.5% of patients immediately after pull-through PEG placement; local metastases were verified at follow-up in 9.4%, all of which were from esophageal squamous cell carcinoma. This risk is particularly high in the older age group and in patients with higher tumor stages. Therefore, pull-through PEG placement should be avoided in these patients and direct access PEG favored instead.

Introduction

Patients with esophageal and oropharyngeal (ENT) malignancies commonly present in a catabolic state secondary to dysphagia, odynophagia, or oropharyngeal obstruction. As the gastrointestinal tract remains functional, enteral feeding is the preferred route of nutritional support. Percutaneous endoscopic gastrostomy (PEG) has superseded nasogastric tube placement and surgical gastrostomy as the commonest method of providing long term enteral feeding [1].

PEG tube insertion was introduced in 1980 by Gauderer et al. and is accepted as the method of choice for enteral nutrition. Some of the many reasons include the minimally invasive approach, the speed and relative ease of insertion, good tolerance and acceptance by patients, as well as the longevity of the tube thus avoiding the need for

replacement [2]. In addition, it is also used for prophylaxis of malnutrition during chemoradiotherapy [3].

Different techniques of PEG placement have been reported, the most widely used being the “pull-through method.” This method uses a catheter with a secure plate at its end, which is pulled through the upper digestive tract and the gastric and abdominal walls to the outside [4]. However, this method allows the secure plate to come into contact with the primary tumor and superficial tumor cells. Case reports and retrospective analysis describe metastases at the PEG insertion site of the abdominal wall, but to the best of our knowledge there is no prospective study available to date. Since the availability of modern treatment options with intention to cure and improved survival rates, possible late PEG complications have become more significant.

The aim of this study was to prospectively and systematically quantify the rate of malignant cell seeding at the abdominal wall pull-through site and to evaluate possible risk factors.

Materials and methods



Patients

A total of 50 consecutive patients with either esophageal or oropharyngeal carcinomas who were referred for PEG placement between May 2011 and June 2012 participated in this study. In a subgroup of 10 patients with esophageal cancer, a high grade stenosis of the esophagus was diagnosed on endoscopy. Therefore, these patients underwent PEG tube placement using the direct introducer technique.

The indication for PEG tube placement was made independently by the referring physician and was unrelated to any possible participation in the study. None of the participants had a history of prior radiotherapy or chemotherapy. All patients received antibiotic prophylaxis with 2g intravenous cefuroxime prior to or during the PEG placement procedure. In addition, 10 patients who underwent PEG placement for neurological disorders served as internal controls.

The study protocol was approved by the Ethics Committee of the Medical Faculty of the Christian Albrecht University and University Hospital Schleswig-Holstein (registration no. D465/11). Written informed consent was obtained from all patients.

Study protocol

Subgroup analyses of primary and late malignant cell seeding included age, location, histology, and initial tumor stage to identify possible risk factors for malignant cell seeding.

Inclusion criteria were: esophageal or oropharyngeal malignancy; metastatic infiltration of any cancer into esophagus, pharynx, or larynx; indication for PEG tube placement; written informed consent for PEG tube placement and for the participation in the study. Exclusion criteria were: age < 18 years; pregnancy; ascites; history of radiotherapy or chemotherapy; coagulopathy (international normalized ratio > 2); no transillumination; gastric ulcer; and/or local tumor infiltration of the gastric mucosa.

PEG tube placement

An esophagogastroduodenoscopy was performed in each patient under general sedation with propofol 1% (Braun Melsungen AG, Melsungen, Germany). The gastrostomy site was chosen by transillumination to ensure that the anterior gastric wall was in direct proximity to the abdominal wall and no tissue or vessel lay between.

Pull-through method

Insertion of a 15 CH feeding tube (Fresenius Kabi; Bad Homburg, Germany) was performed using the standard pull-through technique in all patients as described previously [2,5]. Briefly, after preparation, dressing, and sterilization of the abdominal wall (Sterillium; Bode Chemie GmbH, Hamburg, Germany), the location for the PEG placement was identified by diaphanoscopy. After administration of local anesthesia (10 mL Xylocaine 1%; AstraZeneca, London, UK), a skin incision was made and a 20-G needle with cover sheet was forwarded into the stomach. The inner stylet was removed and a thread brought forward through the hollow inner part of the needle into the stomach before being grasped by biopsy forceps. The endoscope with thread was with-

drawn through the mouth. The thread running from the skin and abdominal wall through the stomach and esophagus and out of the mouth was attached to the PEG tubing with a 24-mm diameter secure bumper at its distal end. By pulling on the thread from the abdominal side, the PEG tube + bumper were pulled back from the mouth through the stomach and abdominal wall to the outside. An external counter plate was applied to fix the tubing. Adequate tension was applied on the system to keep it in place and to avoid acute bleeding. Enteral feeding through the PEG tube was started 6 hours after the procedure.

Direct introducer technique

This technique was used in patients with proof of a high grade stenosis, when the stenosis could only be passed using a small-diameter endoscope (GIF-XP180N; Olympus, Hamburg, Germany). The procedure was performed using the Freka Pexact-15 CH/Fr introducer PEG kit according to the manufacturer's description (Fresenius Kabi). At the site of transillumination, the stomach was punctured using the gastropexy device. With this device two sutures were applied to fix the anterior gastric wall to the anterior abdominal wall. After gastropexy, a trocar was placed between the two sutures into the stomach. The trocar was removed, and a 15-Fr PEG tube was introduced into the plastic sheath. Thereafter, the gastric balloon at the tip of the PEG tube was injected with 5 mL of sterile water. The peel-away sheath was then removed.

Again, an external counter plate was applied to fix the tubing. Adequate tension was applied on the system to keep it in place and to avoid acute bleeding. Enteral feeding through the PEG tube was started 6 hours after the procedure.

Cytology

Immediately after PEG tube placement, cytology samples were taken from two locations. The first sample was taken from the PEG tubing until enough material was obtained to produce at least five slides. The second sample was taken by brush cytology from the incision site at the abdominal wall next to the PEG tubing. This was repeated after 3–6 months.

The samples were air dried and sent for cytological assessment, which was performed by an independent cytologist. May–Grünwald–Giemsa staining was used for evaluation. After microscopic evaluation, cell samples were classified according to the modified Papanicolaou classification (0: not representative; I: absence of atypical or abnormal cells; II: reactive cells, signs of inflammation; III: cell proliferation with atypic cells; IVa: carcinoma in situ; IVb: invasive carcinoma, strongly suggestive for malignancy; V: invasive carcinoma, conclusive for malignancy) [6].

Follow-up

At 3–6 months after PEG tube placement, a follow-up examination was performed if the patient was still alive, the medical condition allowed it, and the patient consented to the examination. Patients' interim medical history, including specific oncological therapy, was recorded and a second brush cytology from the abdominal insertion site was taken to exclude/confirm the presence of abdominal wall metastases. The samples were processed and analyzed as described above.

Statistical analysis

Patient characteristics are reported as means \pm SD, and results are presented as means \pm SEM. A two-sided *P* value of < 0.05 was taken to indicate significant differences. Continuous variables were

Table 1 Patient characteristics.

	Oropharyngeal	Esophagus
Number of patients, n	26	24
Age, mean \pm SD, years	64.9 \pm 10.5	63.8 \pm 11.2
Sex, m/f, n	16/10	16/8
Esophagus, n		
SCC	–	11
Adenocarcinoma	–	13
Oropharyngeal, n		
Oral SCC	14	–
Laryngeal SCC	4	–
Pharyngeal SCC	8	–
Tumor stage, n		
UICC I	0	0
UICC II	1	1
UICC III	12	18
UICC IV	13	5

SCC, squamous cell carcinoma; UICC, International Union Against Cancer staging.

compared using the Student's *t* test. Statistical analyses were carried out using GraphPad Prism, version 4.0 (GraphPad Software, San Diego, California, USA).

Results

Patients

The mean age of the 50 patients (32 male, 18 female) was 64.4 \pm 10.7 years. There were no significant differences in age between the two groups of patients ($P=0.27$) and the controls ($P=0.85$). The ENT cancer group comprised 26 patients with either oral ($n=14$), laryngeal ($n=4$), or pharyngeal ($n=8$) squamous cell cancers (SCC). The esophageal cancer group comprised 24 patients with either SCC ($n=11$) or adenocarcinoma ($n=13$). In this group one patient had direct infiltration of a non-small cell lung cancer (adenocarcinoma) into the mid-third of the esophagus, thus no esophageal primary.

In 48 of the 50 patients, UICC cancer stage was III or IV. In the oropharyngeal cancer group only one patient presented with UICC stage II, 12 patients had stage UICC III, and 13 had UICC stage IV. In the esophageal cancer group, 1 patient was UICC stage II, 18 patients UICC stage III, and 5 patients UICC IV. Details are presented in [Table 1](#).

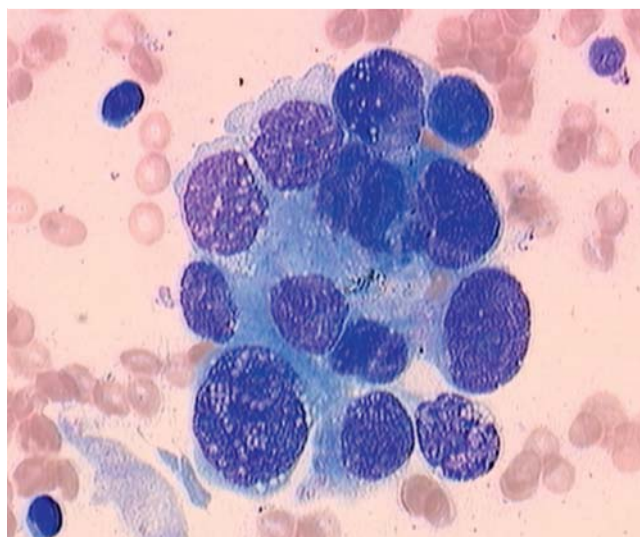


Fig. 1 Cytological image of esophageal squamous cell cancer cells on brush cytology immediately after percutaneous endoscopic gastrostomy tube implantation ($\times 200$).

PEG tube placement

PEG tube implantation was successful in all 50 patients (100%). No major complications such as infection, perforation, or bleeding were reported during the study.

Tumor cell seeding

Smears from the PEG tube or brush cytology of the incision site immediately after PEG placement showed tumor cells in 22.5% of patients in the pull-through method group (9/40) ([Fig. 1](#), [Fig. 2a](#)). A transfer of malignant cells by the PEG tube occurred in 5/26 (19.2%) in the oropharyngeal cancer group and in 4/14 (28.6%) cases in the esophageal cancer group ($P=0.69$). Histological and local differences are shown in [Table 2](#).

None of the patients who underwent PEG placement using the direct introducer technique had malignant cells on cytology immediately after the insertion. Furthermore, no malignant cells were detected in the control group using the pull-through method for PEG placement.

Follow-up

It was possible to re-examine 41/50 patients (82.0%) after a mean time of 16.4 \pm 0.5 weeks (range 11–24): 32/40 in the pull-through group (80.0%) and 9/10 in the direct introducer group (90.0%). The remaining nine patients were either lost to follow-up ($n=3$) or died during the observation period ($n=6$). The non-

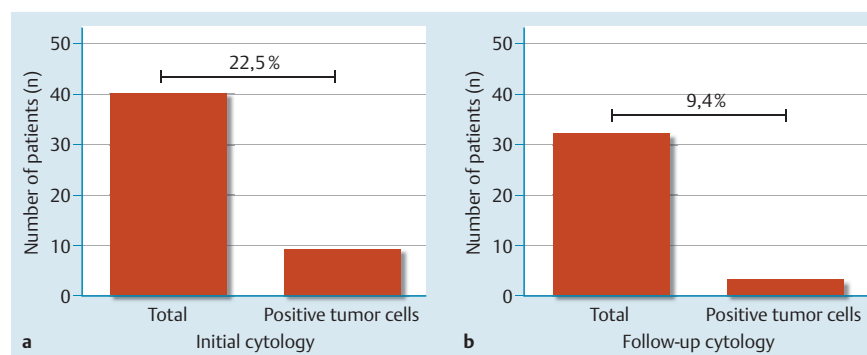


Fig. 2 Comparison of patients with proof of malignant cells on cytology to total number of patients after percutaneous endoscopic gastrostomy placement using the pull-through method. **a** Initial cytology. **b** Cytology at follow-up.

malignant causes of deaths were ischemic heart attack (n = 1) and pulmonary embolism (n = 1); the other patients died due to their progressive malignant disease.

Among the 32 patients in the pull-through group who were re-examined, malignant cells were found on brush cytology of the incision site in three patients (9.4%) with SCC. The other patients had benign smears (11 PAP I, 18 PAP II) (Fig. 2b). None of the patients had macroscopically visible tumor masses at follow-up. Nine of the 10 patients in the direct introducer group were re-examined. None of these patients had malignant cells on brush cytology (5 PAP I, 4 PAP II). The control group was re-examined after a mean follow-up period of 12.2 ± 0.3 weeks. No signs of malignant cells were observed on brush cytology (7 PAP I, 3 PAP II).

Risk factors for tumor cell seeding

The mean age of patients with negative results on cytology was 63.7 ± 11.4 years. Though the difference was not significant, patients with malignant cell seeding tended to be 7 years older than the control group (mean age 70.4 ± 3.2 years; $P = 0.1$) (Fig. 3). Seven of the nine patients (77.8%) with a positive cytology were male. Initial malignant cell seeding occurred in 28.6% of patients with esophageal cancer (SCC 50% [3/6]; adenocarcinoma 12.5% [1/8]) and 19.2% with ENT SCC (oral SCC 14.3% [2/14]; pharyngeal SCC 37.5% [3/8]).

After follow-up, local tumor cell seeding at the abdominal wall was seen exclusively in patients with SCC (one oral SCC and two esophageal SCC). Therefore, although the sample size may be too small to predict, SCC may predispose a patient to early and late malignant cell seeding.

Malignant cells at the abdominal wall after follow-up occurred only in patients who had evidence of malignant tumor spread on initial cytology. All patients with benign smears at the first examination remained negative at follow-up.

Comparison of the rate of malignant cell seeding with initial tumor stages showed a higher risk for patients with UICC stages III and IV compared with UICC stages I and II.

In summary, overall and subgroup analyses of initial and late malignant cell seeding revealed that age, tumor type, and initial tumor stage were risk factors for seeding.

Chemotherapy

Among the 24 patients with esophageal cancer who were included, nine patients (37.5%) underwent systemic chemotherapy and eight (33.3%) received combined radio-/chemotherapy. Seven patients (29.2%) did not receive any specific antitumor therapy but were transferred to best supportive care.

None of the patients in the ENT group was treated with systemic chemotherapy alone, 22 patients (84.6%) received a combination of radio- and chemotherapy. Only four patients (15.4%) received best supportive care. Details are shown in Table 3.

Total	Chemotherapy n, (%)	Radio-/chemotherapy n (%)	No therapy n (%)
Esophagus	9 (37.5)	8 (33.3)	7 (29.2)
SCC (n = 11)	0 (0)	8 (72.7)	3 (27.3)
Adenocarcinoma (n = 13)	9 (69.2)	0 (0)	4 (30.8)
Oropharyngeal	0 (0)	22 (84.6)	4 (15.4)
Oral SCC (n = 14)	0 (0)	12 (85.7)	2 (14.3)
Laryngeal SCC (n = 4)	0 (0)	4 (100)	0 (0)
Pharyngeal SCC (n = 8)	0 (0)	6 (75.0)	2 (25.0)

SCC, squamous cell carcinoma.

Table 2 Patients with positive tumor cells on cytology following percutaneous endoscopic gastrostomy tube placement using the pull-through technique.

Pull-through technique	Total, n	Positive tumor cells, n (%)
Total	40	9 (22.5)
Esophagus, n	14	4 (28.6)
SCC	6	3 (50)
Adenocarcinoma	8	1 (12.5)
Oropharyngeal, n	26	5 (19.2)
Oral SCC	14	2 (14.3)
Laryngeal SCC	4	0 (0)
Pharyngeal SCC	8	3 (37.5)

SCC, squamous cell carcinoma.

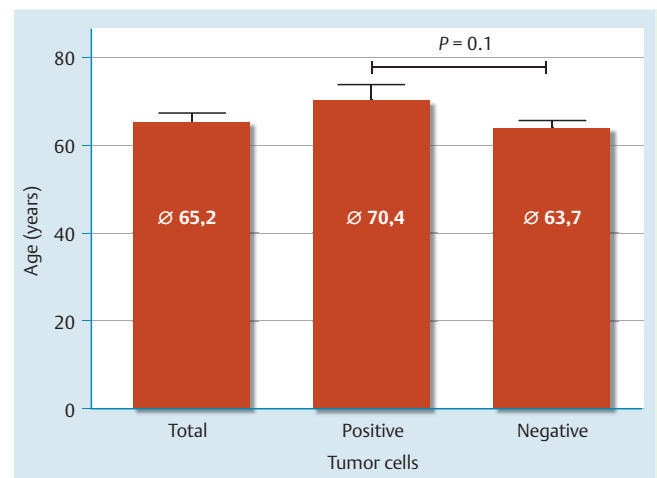


Fig. 3 Age comparison of total number of patients and patients with positive or negative results on cytology. Ø, mean age (years).

None of the three patients with proof of malignant cells on brush cytology after follow-up received systemic chemotherapy, only best supportive care. Therefore, nesting of tumor cells in the abdominal wall after pull-through PEG insertion could be prevented by systemic chemotherapy.

Survival

By the end of the study, survival data were only available for seven patients, two of whom presented with malignant cell seeding at the time of follow-up. The median overall survival of these seven patients was 21 weeks with a mean survival of 23.7 ± 2.9 weeks. There was a marked difference in the mean overall survival (OS) between the patients without and those with proof of malignant cell seeding at follow-up ($OS_{\text{mean negative}} = 26.8 \pm 2.9$ weeks vs. $OS_{\text{mean positive}} = 16 \pm 1.0$ weeks); However, due to the

Table 3 Overview of patients receiving chemo-/radiotherapy.

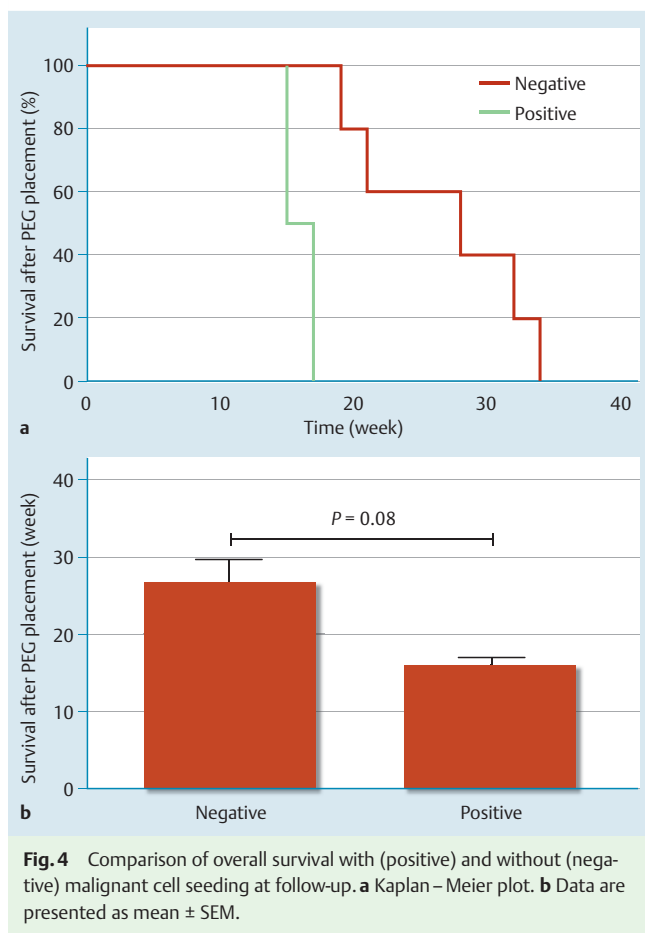


Fig. 4 Comparison of overall survival with (positive) and without (negative) malignant cell seeding at follow-up. **a** Kaplan–Meier plot. **b** Data are presented as mean \pm SEM.

small sample size, the difference failed to reach statistical significance ($P=0.08$) (● Fig. 4).

Discussion

Several case reports and retrospective analyses have shown that patients with esophageal and oropharyngeal cancers who underwent PEG placement using the pull-through technique carry a risk of development of abdominal wall metastasis. However, due to lack of prospective studies it remains unknown whether this is an uncommon late complication or whether, if analyzed systematically, it might represent a rather more common occurrence. In the present study, the rate of malignant cell seeding was quantified in a prospective fashion for the first time. In addition, it was also possible to identify several risk factors that might predispose a patient to the development of malignant cell seeding.

A Medline search revealed reports of more than 50 cases of abdominal wall metastases after PEG placement. As most of these were case reports, the exact rate of metastasis remains unknown. In a retrospective analysis, Cruz et al. evaluated the incidence of abdominal wall metastases following PEG placement in 304 patients with head and neck cancer, of whom 218 had active disease and a viable tumor in the oropharynx or hypopharynx when the PEG was placed [17]. Metastases were proven in 2/218 (0.92%). However, abdominal wall metastasis was defined as macroscopic evidence of tumor masses on clinical examination or endoscopy. No cytology/histology was taken from the insertion site leaving the true rate of malignant cell seeding unclear.

In the present study, malignant cell seeding was defined as proof of tumor cells on cytology either immediately after PEG insertion or at least 3 months after. In 22.5% of patients, malignant cell transfer to the abdominal incision site was demonstrated, and abdominal wall metastases were present in 9.4% after 3–6 months; however, at follow-up none of the patients had macroscopically visible tumor masses.

Comparing published case reports and retrospective data with the present prospective study suggests that the risk of malignant cell translocation due to PEG placement seems to be underestimated.

Different modes of tumor spread have been discussed that may predispose an individual to PEG site metastasis: (1) direct implantation of tumor cells by the PEG tube, (2) desquamation of malignant cells into the gastrointestinal tract, (3) hematogenous spread. As the secure plate often comes into contact with superficial tumor cells in patients with esophageal and oropharyngeal malignancies using the pull-through technique, a direct mechanical translocation of malignant cells to the abdominal wall is the most likely mechanism. Direct implantation of tumor cells often occurs after diagnostic and therapeutic procedures. In line with this hypothesis, all cases reported to date used the pull-through method for PEG tube placement [8,9]. Evidence also exists for hematogenous and lymphatic dissemination of cancer cells [10–12]. In the present study, malignant cell seeding could only be proved in the follow-up samples of patients who had initial transfer of malignant cells to the incision site. Therefore, direct mechanical implantation of cancer cells is the most likely mode of tumor spread in these patients.

Constant shedding of tumor cells, which then migrate into the incision tract, could be an additional mode of malignant cell spread. As none of the patients who underwent direct PEG placement had evidence of malignant cells at the incision site, either directly after PEG tube insertion or at the time of follow-up, this mechanism is unlikely.

Survival data were obtained from a small number of patients ($n=7$). Of note, proof of malignant cells at follow-up resulted in a shortened median overall survival in the present study ($OS_{\text{mean negative}}=26.8\pm 2.9$ weeks vs. $OS_{\text{mean positive}}=16\pm 1.0$ weeks), though, due to the rather small sample size, this difference failed to reach statistical significance ($P=0.08$). At follow-up, the rate of bleeding, gastrointestinal obstruction, or PEG-related pain remained unchanged in patients with or without malignant cell seeding in the PEG tract. As a consequence of the reduced overall survival caused by malignant cell seeding, direct PEG placement should be favored even in patients with metastatic, incurable disease. Further studies are needed that specifically address this question. In the present study several possible risk factors were evaluated for the development of malignant cell translocation after PEG tube placement, including tumor location (oropharyngeal cancer), tumor type (SCC), and advanced tumor stages (UICC III and IV) in predominantly male patients. Though statistically not significant, patients with abdominal site metastasis tended to be older than patients without any evidence of malignant cells on cytology. These findings stand in line with a review of 44 published cases of stomal metastasis after PEG insertion. Though the reported cases were significantly younger than in the present study population (59 ± 10.0 years vs. 70.4 ± 9.7 years), 79% of patients with local metastasis after PEG implantation were male. Furthermore, in the reported cases, pharyngoesophageal location of primary cancer (100%), squamous cell histology (98%), poorly differentiated tumor cells (92%), advanced pathological stage

Table 4 Patients with positive cytology results (present study) compared with 44 published cases in the literature (Cappell et al., 2007 [13]).

	Present study	Cappell et al.
Age, mean ± SD, years	70.4 ± 9.7	59.0 ± 10.0
Sex, % (n/N)		
Male	78 (7/9)	79
Female	22 (2/9)	21
Primary tumor, %		
Oropharynx	55	71
Esophagus	45	29
Histology, %		
SCC	100	98
Adenocarcinoma	0	2
Pathological stage, %		
Early stage	0	3
Advanced stage	100	97
Previous therapy, %		
Yes	0	0
No	100	100

SCC, squamous cell carcinoma.

(97%), and large primary cancer size were identified as strong risk factors for the development of stomal metastasis. The results are summarized in **Table 4** [13].

These results and our own data suggest that in patients having these risk factors for malignant tumor cell seeding, an alternative route for PEG placement should be used to avoid direct contact of the PEG tube or secure plate with superficial tumor cells. Pickhardt et al. have discussed the advantages of percutaneous radiologic gastrostomy placement, in which direct contact of the tube with the primary tumor is avoided [14]. An alternative endoscopic approach was described by Dormann et al., using an introducer PEG in combination with an endoscopic gastropexy, as described previously [15, 16].

A retrospective analysis in 299 patients undergoing PEG placement compared the complication rates between the PEG pull-through and introducer techniques with gastropexy. Short term complications were encountered in 11/24 patients (45.7%) undergoing introducer PEG placement compared with 4/33 patients (12.1%) undergoing the pull-through method ($P=0.004$) [17]. The rates of local infections, bleeding, and perforation were not statistically different between the insertion techniques. The mortality rate tended to be higher following the introducer technique than after the pull-through technique. In the study two patients died (respiratory complications after surgical rescue) after PEG placement using the introducer technique, resulting in an overall mortality rate of 8% vs. 0% with the pull-through technique ($P=0.091$) [17].

Review of the presented cases and retrospective analyses showed that abdominal site metastasis only occurred in patients with viable tumors without previous chemotherapy or radiotherapy. Therefore, a possible option would be to include chemotherapy or chemoradiotherapy prior to PEG placement in patients with an intention to cure. So far, no studies are available evaluating this topic.

Conclusion

This study proved a high rate (22.5%) of direct malignant seeding in patients with esophageal and ENT cancers immediately after pull-through PEG tube placement and 9.4% of malignant cell

seeding at follow-up. All of these were in patients with SCC. This risk is particularly high in older patients and those with higher tumor stages. Therefore, direct placement of PEG tubes or prior radio-/chemotherapy should be favored in this group of patients despite the markedly higher complication rate. Larger studies are necessary to confirm these data.

Competing interests: None.

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