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Item Type	Journal article
Authors	Boylan, Conor;Barrett, Diane;Li, Vincent;Merrick, Susan;Steed, Helen
Citation	Boylan, C., Barrett, D., Li, V., Merrick, S. and Steed, H. (2021) Longitudinal complications associated with PEG: rate and severity of 30-day and 1-year complications experienced by patients after primary PEG insertion. <i>Clinical Nutrition ESPEN</i> . 43, pp.514-521. https://doi.org/10.1016/j.clnesp.2021.02.004
DOI	10.1016/j.clnesp.2021.02.004
Publisher	Elsevier
Journal	Clinical Nutrition ESPEN
Download date	2026-03-10 04:21:05
License	https://creativecommons.org/licenses/by-nc-nd/4.0/
Link to Item	http://hdl.handle.net/2436/623965

Longitudinal Complications Associated with PEG: Rate and Severity of 30-day and 1-year Complications Experienced by Patients After Primary PEG Insertion

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Word count for manuscript (excluding tables and references): 3263 words

Abstract

Background and Aims

Percutaneous Endoscopic Gastrostomy (PEG) feeding is utilised in patients with exceptionally poor oral intake but is associated with both short and long-term complications. This study reviews longitudinal PEG complications and compares key subgroups.

Methods

Single-centre retrospective observational study of all patients receiving PEG insertion between January 2016 and December 2018.

Results

306 patients met the inclusion criteria. The mean age at insertion was 67 years. The majority were cared for in their own home (80.4%) by themselves or family (74.9%). 127 PEG tubes were inserted for dysphagia and 165 prophylactically prior to treatment for head and neck cancer.

In the first 30 days 16.7% experienced a complication. The most frequently reported was peristomal pain (9.2%). In the first year, 35.6% experienced at least one complication, 12.4% two complications and 6.6% three complications and 6.5% required inpatient treatment for their complication. The most common was pain (14.4%) followed by site weeping, site infection and external overgranulation. Patients with dysphagia took longer to develop complications, had fewer complications and took longer to require management by members of the secondary care team than those with head and neck cancer.

Discounting peristomal pain, there was no difference in total complications between patients caring for themselves when compared to those receiving professional input.

Conclusion

One third of patients will experience a complication related to their PEG tube over 1 year, but the majority are managed in an outpatient setting. This study has implications for planning support services and consenting and counselling patients pre-PEG-insertion.

Keywords (5)

Percutaneous endoscopic gastrostomy; complications; mortality; deglutition disorders; head and neck neoplasms;

Word count for abstract: 252 words

Introduction

A percutaneous endoscopic gastrostomy (PEG) tube is a method of enteral nutrition whereby a feeding tube is introduced into the anterior abdominal wall to communicate directly with the stomach¹. The specific techniques vary, but in all cases insertion of the tube and appropriate positioning are both monitored and assisted using an endoscopic camera and apparatus.

The indications for insertion of a PEG are many, but they are typically utilised when assisted feeding is anticipated to be required for >30 days and when nasoenteric feeding is considered unfeasible². Common conditions necessitating insertion of a PEG tube include dysphagia resulting from cerebrovascular disease, neurological deficit such as multiple sclerosis or motor neurone disease, psychomotor retardation and cancer of the head and neck³. In head and neck cancer, the tube is typically inserted prophylactically due to either anticipated mucositis resulting from radiotherapy, the obstructive properties of the tumour or planned major reconstructive surgery.

While PEG feeding undoubtedly holds many benefits over long-term nasoenteric feeding⁴, it is not without complications. Previous studies have tended to focus on the major complications related to or occurring at the time of physical insertion of the device, with only a minority reviewing longer-term complications. The rates of peristomal site infection are reported to range from 2.3% to 27.9%⁴⁻⁹, tube leakage to range from 0.0% to 6.8%^{4-6,8,9}, dislodgement to be 12.8%¹⁰ and minor bleeds to range from 1.4% to 9.7%⁶⁻⁸ at 30-days. In addition, the 30-day mortality has been reported to be between 1.8 to 5.0%^{6,11,12}.

Jafari et al report on a large cohort of 641 PEG insertions over a 7-year period and show a complication rate of 9.4%¹³. Additionally, Ermis et al report complication rates of 21% with

some patients being followed up to 12 months, but the range of follow up data varies significantly from 3 days to 78 months and the cohort is relatively small (n=81)¹⁴. This data is supported by other studies that describe late complications but follow up periods and data capture is usually inadequately described.

Other methods of gastrostomy insertion, such as radiologically inserted gastrostomy tubes, are comparable to PEG tubes in terms of major and minor complications, but have higher rates of tube dislodgement and requiring replacement^{15,16}.

It is necessary to investigate and understand the type and frequency of complications arising from PEG insertion in order to provide appropriate pre-insertion counselling and plan cost-effective support services and post-insertion management¹⁷. Furthermore, long-term follow up over a period greater than 30 days is essential to understand and anticipate the numerous complications that may not present until later in the lifetime of the PEG tube.

This study reports the rates of all complications arising from PEG usage in terms of 30-day and 1-year incidence. It compares common subgroups to investigate the differences in their presentations. It also reports the severity of these complications and suggests the implications for clinical practice.

Materials and Methods

Setting

This is a retrospective observational study taking place at a single UK National Health Service (NHS) Trust; an organizational unit within the NHS responsible for providing care for a geographical population of approximately 500,000. All primary and secondary care attendances and admissions are captured on an electronic health record for patients within this area. Secondary care patients are served by a hospital-based nutrition team. The bulk of

community enteral tube cases are triaged by the nutrition team and requests are sent to the contracted healthcare company to manage the patient. Subsequently, these records were not available to the research team.

All decisions to insert a PEG tube are reviewed and made at an enteral nutrition multidisciplinary meeting attended by a consultant gastroenterologist lead physician, enteral nutrition nurses, dieticians, speech and language therapists and a palliative care nurse.

Identification of patients and data extraction

We undertook a retrospective review of the gastrointestinal Reporting Tool UNISOFT to identify all patients who underwent a PEG insertion between January 2016 and December 2018. For the purposes of UK ethical approval requirements, this is classified as a retrospective eMR quality review and formal National Health Service Research Ethics Committee approval was not required.

The participants then had their electronic hospital and primary practitioner health records reviewed and the inclusion and exclusion criteria were applied prior to extraction of the required dataset. Data were collected from the time of insertion to present day, or to a specified endpoint such as death or removal of the PEG tube.

When patient data was missing, we liaised with the local community team in an effort to provide as complete a dataset as possible. Where patients had moved out of area, we contacted the team that had received the patient and requested follow up data from them.

Data were collected on demographics of the individual and information related to the PEG. This includes indications for insertion/removal and complications occurring within 30 days post-insertion, 0-365 days post-insertion, >1-year post-insertion and 30-days post-removal

where applicable. The type, severity and time for each complication to develop were calculated and recorded.

Inclusion and exclusion criteria

Participants were included if they were 18 years or older, had a primary Freka® CH/FR 15 PEG ENFit® tube inserted using the Ponsky method and had at least 1-year complete follow up from the time of insertion. Exclusion criteria were replacement PEG tubes, removal of PEG tubes, insertion at another NHS organisation, a lack of complete follow up data, inconsistency in note taking, and use of a different feeding method.

It is not UK policy to place PEG in patients with dementia, where dementia is advanced or the primary cause of the reasons for deterioration. No patients in this study had a primary cause of dementia as a cause for their dysphagia or swallow impairment.

Elimination of bias

Selection bias was reduced by applying and adhering to strict inclusion and exclusion criteria. Participant characteristics collected were as full as possible to identify individual factors contributing to outcomes. Confounders were eliminated where possible in statistical analysis.

Severity of complications

In the absence of any formal validated or recognised scoring system for PEG complication evaluation each complication was graded as either *mild*, *moderate*, or *severe*. Criteria for each are:

1 = Mild (treated in the community or left to resolve itself)

2 = Moderate (required review/treatment by members of the secondary care team)

3 = Severe (required an invasive procedure/inpatient care to correct)

Definitions

For consistency and validity of data collection a series of terms were pre-defined by the researchers. Complications were subdivided into mechanical ones related to physical problems with the tube itself or patient-experienced ones.

The dysphagia subgroup was predominantly made up of acute stroke patients and those with deteriorating swallow due to neurological disorders such as multiple sclerosis, Parkinson's disease and motor neurone disease, amongst others. It also included patients with pharyngeal pouches and other anatomical abnormalities that impacted swallowing.

Pain was defined as any patient or carer of a patient specifically reporting pain or significant discomfort at the peristomal site. Gastric bleed was defined as visible blood in the form of haematemesis or melena. A displaced tube was defined as one that had been removed from its normal position enough to require resetting by a carer or medical professional. Struggling to advance was defined as a tube that was reportedly hard to advance but was not found to be clinically buried at that time.

A weeping/irritated site was recorded when no concurrent site infection was identified. A patient was classed as unable to adhere if they were interfering with the tube, were unable to follow standard tube care advice or specifically described being unable to tolerate the tube. Vomiting/reflux and changes in stool composition were only recorded if they could be verified to be PEG-related.

The only "other" recorded was the presence of blood in the tube.

Statistical Analysis

Basic statistics such as averages, standard deviation (SD), interquartile range (IQR) and percentages were calculated using *Microsoft Excel for Office 365* (Microsoft Corporation, 2018. Microsoft Excel, Available <https://office.microsoft.com/excel>)¹⁸. All other statistical analysis was performed using the *Statistical Package for Social Sciences 26 (SPSS26)* software (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp)¹⁹.

Averages are reported as means and medians where appropriate with corresponding SD and IQR. Univariable analysis used Fisher exact tests for nominal and ordinal data and student's t test for continuous data. Survival analysis was performed using Kaplan-Meier plots and outcome predictors were calculated using logistic regression. Kaplan-Meier plots were calculated using the longest available follow up data for each patient.

All statistical tests were two-tailed and $P < .05$ was considered statistically significant throughout the study.

Results

A total of 319 patients were selected from the hospital database and 306 were deemed to meet the inclusion criteria. See figure 1 for flow of patients through the study.

For the whole cohort, 16.7% of patients experienced at least one complication in the first 30-days and 35.6% experienced at least one complication in the first year. The median follow up period was 314.5 days (IQR 337.75).

Participant Characteristics

Baseline characteristics for all participants are given in Table 1. Patients having their PEG inserted due to dysphagia were statistically significantly more likely to be receiving professional care than those having a PEG due to head and neck cancer ($P<.001$).

Characteristic	Whole cohort (n=306)
Age at Insertion, years, mean (SD)	67.3 (13.2)
Male, N (%)	192 (62.7)
Place of Living, N (%)	
Own Home	246 (80.4)
Nursing Home	35 (11.4)
Care Home	22 (7.2)
Other	3 (1.0)
Primary PEG carer, N (%)	
Self	123 (40.2)
Professional Carer	64 (20.9)
Family	59 (19.3)
Self/Family	47 (15.4)
Family/Professional Carer	6 (1.96)
Self/Professional Carer	3 (1.0)
Unknown	4 (1.3)
Indication for Insertion, N (%)	
Head and neck cancer	165 (53.9)
Dysphagia (CVA)	64 (20.9)
Dysphagia (unspecified)	38 (12.4)
Dysphagia (neuromuscular disease)	22 (7.2)
Dysphagia (mechanical)	3 (1.0)

Characteristic	Whole cohort (n=306)
Other	12 (3.9)
Unknown	2 (0.7)

Table 1: Table of participant characteristics. CVA, cerebrovascular accident; PEG, percutaneous endoscopic gastrostomy; SD, standard deviation.

Complication Rates and Severity

The incidence of complications over 30-day follow up for all patients and the dysphagia, head and neck cancer, self/family care and professional care subgroups are given in Table 2.

Just under 17% of all patients recorded at least one complication at 30-day follow up. The most commonly experienced complication was peristomal pain, which was recorded in 9% of patients. This was followed by a weeping/irritated site, site infection and a leaking tube.

Patients in the dysphagia subgroup experienced a lower percentage of complications than the full cohort average and a statistically significantly lower percentage of complications than the head and neck cancer subgroup ($P=.004$). In particular, pain was much less frequently recorded for patients with dysphagia than those with head and neck cancer ($P=.002$). No other statistically significant differences were found. Patient and mechanical complications were similarly distributed between dysphagia and head and neck cancer subgroups ($P=.07$).

A slightly higher proportion of patients experienced complications in the self/family care group compared to the professional care group, although this did not reach statistical significance ($P=.28$). No statistically significant differences were found for any individual complications. Patient and mechanical complications were similarly distributed between self/family care and professional care subgroups ($P=.65$).

Complications	Recorded events at 30 days						
	All Patients (n=306)	Dysphagia (n=127)	Head and Neck Cancer (n=165)	P-value*	Self/Family Care (n=229)	Professional Care (n=73)	P-value*
	N (%)	N (%)	N (%)		N (%)	N (%)	
No	255 (83.3)	115 (90.6)	128 (77.6)		187 (81.7)	64 (87.7)	
Yes	51 (16.7)	12 (9.4)	37 (22.4)	.004	42 (18.3)	9 (12.3)	.28
Patient							
Pain	28 (9.2)	4 (3.1)	23 (13.9)	.002	24 (10.5)	4 (5.5)	.25
Weeping/irritated site	10 (3.3)	3 (2.4)	7 (4.2)	.52	8 (3.5)	2 (2.7)	1.00
Site infection	4 (1.3)	2 (1.6)	2 (1.2)	1.00	2 (0.9)	2 (2.7)	.25
External overgranulation	3 (1.0)	1 (0.8)	2 (1.2)	1.00	3 (1.3)	0	1.00
Unable to adhere	3 (1.0)	0	1 (0.6)	1.00	2 (0.9)	1 (1.4)	.57
Vomiting/reflux	3 (1.0)	0	3 (1.8)	.26	3 (1.3)	0	1.00
Change in stool composition	1 (0.3)	0	1 (0.6)	1.00	1 (0.4)	0	1.00
Gastric bleed	1 (0.3)	0	1 (0.6)	1.00	1 (0.4)	0	1.00
Aspiration pneumonia	1 (0.3)	1 (0.8)	0	.43	0	1 (1.4)	.24
Mechanical							
Leaking tube	4 (1.3)	1 (0.8)	3 (1.8)	.64	4 (1.7)	0	.58
Damaged tube	2 (0.7)	2 (1.6)	0	.19	0	2 (2.7)	.06
Displaced tube	1 (0.3)	1 (0.8)	0	.43	1 (0.4)	0	1.00
Blocked tube	0	0	0	-	0	0	-
Struggling to advance	0	0	0	-	0	0	-
Buried bumper	0	0	0	-	0	0	-
Other ¹	1 (0.3)	0	0	-	1 (0.4)	0	1.00

Table 2: Recorded complications for all patients and subgroup patients at 30-day follow up. Patients that did not complete 30-day follow up but still experienced a complication in this period are also recorded. Individual complications are only reported one time per patient, even if a patient experienced a particular complication multiple times. *P-values are calculated using Fisher's exact test. ¹Other = "blood in tube".

Recorded events at 1 year							
Complications	All Patients	Dysphagia	Head and	<i>P</i> -value*	Self/Family	Professional	<i>P</i> -value*
	(n=306)	(n=127)	Neck Cancer		Care	Care (n=73)	
	N (%)	N (%)	N (%)		N (%)	N (%)	
No	197 (64.4)	91 (71.7)	97 (58.8)		138 (60.3)	55 (75.3)	
Yes	109 (35.6)	36 (28.3)	68 (41.2)	.03	91 (39.7)	18 (24.7)	.02
Patient							
Pain	44 (14.4)	7 (5.5)	35 (21.2)	<.001	38 (16.5)	6 (8.2)	.09
Weeping/irritated site ¹	28 (9.2)	11 (8.7)	17 (10.3)	.69	24 (10.5)	5 (6.8)	.49
Site infection	20 (6.5)	11 (8.7)	9 (5.5)	.35	17 (7.4)	3 (4.1)	.42
External overgranulation	20 (6.5)	5 (3.9)	15 (9.1)	.10	16 (7.0)	4 (5.5)	.79
Unable to adhere	4 (1.3)	1 (0.8)	1 (0.6)	1.00	3 (1.3)	1 (1.4)	1.00
Vomiting/reflux ²	11 (3.6)	1 (0.8)	8 (4.8)	.08	9 (3.9)	2 (2.7)	1.00
Change in stool composition ²	3 (1.0)	0	3 (1.8)	.26	3 (1.3)	0	1.00
Gastric bleed	3 (1.0)	0	2 (1.2)	.51	2 (0.9)	1 (1.4)	.57
Aspiration pneumonia	2 (0.7)	2 (1.6)	0	.19	1 (0.4)	1 (1.4)	.43
Mechanical							
Leaking tube	7 (2.3)	1 (0.8)	5 (3.0)	.24	6 (2.6)	1 (1.4)	1.00
Damaged tube	13 (4.2)	7 (5.5)	6 (3.6)	.57	8 (3.5)	5 (6.8)	.32
Displaced tube	2 (0.7)	1 (0.8)	0	.43	1 (0.4)	1 (1.4)	.43
Blocked tube	3 (1.0)	1 (0.8)	1 (0.6)	1.00	2 (0.9)	1 (1.4)	.57
Struggling to advance ³	2 (0.7)	1 (0.8)	1 (0.6)	1.00	2 (0.9)	0	1.00
Buried bumper	1 (0.3)	1 (0.8)	0	.43	0	1 (1.4)	.24
Other ⁴	1 (0.3)	0	1 (0.6)	1.00	1 (0.4)	0	1.00
End Point							
Mortality							
30-day, N (%)	13 (4.2)	10 (7.9)	2 (1.2)	.01*	7 (3.1)	4 (5.5)	.31*
1-year, N (%)	87 (28.4)	46 (63.2)	37 (22.4)	.01*	53 (23.1)	30 (41.1)	.004*
Time to death, median (IQR)	181 (273.5)	108 (219)	233 (260)	.28†	211 (263.75)	156 (230)	.56†

Complications	Recorded events at 1 year						
	All Patients (n=306) N (%)	Dysphagia (n=127) N (%)	Head and Neck Cancer (n=165) N (%)	<i>P</i> -value*	Self/Family Care (n=229) N (%)	Professional Care (n=73) N (%)	<i>P</i> -value*
Removal							
30-day, N (%)	0	0	0	-	0	0	-
1-year, N (%)	86 (28.1)	23 (18.1)	61 (37.0)	<.001*	78 (34.1)	8 (11.0)	<.001*
Time to removal, median (IQR)	262.5 (177.5)	226 (252)	267.5 (140.5)	.12 [†]	256 (181)	299 (237)	.30 [†]

Table 3: Recorded complications for all patients and subgroup patients at 1-year follow up and end points for all patients and subgroup

patients. Patients that did not complete 1-year follow up but still experienced a complication in this period are also recorded. Individual

complications are only reported one time per patient, even if a patient experienced a particular complication multiple times. **P*-values are

calculated using Fisher’s exact test. †*P*-value calculated using student’s t test. ¹Other = “blood in tube”. IQR, interquartile range.

The incidence of complications over 1-year follow up for all patients and the dysphagia, head and neck cancer, self/family care and professional care subgroups are given in Table 3.

At 1-year follow up one third (36%) of all patients experienced at least one complication. The most common of these was still peristomal pain, followed by a weeping/irritated site, site infection and external overgranulation. 39 patients (12.4%) experienced two or more complications and 20 (6.6%) experienced 3 or more complications.

The dysphagia subgroup again had a statistically significantly lower proportion of patients reporting complications in this follow up period than the head and neck cohort ($P=.03$). They also had a much lower recorded incidence of pain ($P<.001$). All other individual complications were comparable. There were no reports of seeding from the head and neck cancers. Patient and mechanical complications were similarly distributed between dysphagia and head and neck cancer subgroups ($P=.11$).

Overall, patients in the self/family care subgroup reported significantly higher numbers of complications than those in the professional care subgroup ($P=.02$). This was not significantly biased towards any particular complication, and no more statistically significant differences were found. Patient and mechanical complications were similarly distributed between self/family care and professional care subgroups ($P=.12$).

The median time to develop peristomal pain was 22 days (IQR 86), and cases were treated almost equally in the community (49.1%) or by members of the secondary care team (47.2%). The median time to develop a weeping/irritated site was 64 days (IQR 123.5) and 62.9% of cases were treated in the community. The median time for a site infection was 71 days (IQR 143), with 60.0% of cases being treated in the community, 24.0% by members of the

secondary care team and 16.0% requiring an invasive procedure. The median time for external overgranulation to develop was 106 days (IQR 303), with 40.7% being treated in the community, 51.9% by members of the secondary care team and 7.4% requiring an invasive procedure.

Swab results are available for 46 accounts of peristomal site infection. The most common result was skin flora (34.8%), whilst the most commonly detected organisms were *Staphylococcus aureus* (in 21.7%), followed by *Candida albicans* and non-albicans candida species (both in 10.9%). MRSA was recorded in 1 patient.

Severity of complications for all patients over 30-day and 1-year follow up are given in Table 4. It can be seen that over the whole follow up period, at least half of the complications were dealt with solely within the community by members of the nursing or primary care teams. For 1-year follow up, a greater proportion of patients required inpatient care to treat their complication, although this did not reach statistical significance ($P=.19$).

The time to develop any complication and a type 1, 2 or 3 complication was analysed for the dysphagia, head and neck cancer, self/family care and professional care subgroups and is given in figures 2 and 3 respectively.

Those in the dysphagia subgroup took longer to develop at least one complication ($P=.04$) and longer to specifically develop a type 2 complication ($P=.03$) than those in the head and neck cancer subgroup. There was no statistically significant difference in the time to develop a type 1 or type 3 complication between the two groups. There were no statistically significant differences in the time to develop any complications between the self/family care and professional care subgroups.

Backwards input multivariable binary logistic regression was used to test for significant predictors of developing any complication type. Using this method, higher age at PEG insertion was found to be a significant predictor of developing at least one complication ($P=.001$) and requiring professional nursing care was a significant predictor of developing at least one type 1 complication ($P=.01$). No significant predictors were found for developing type 2 or type 3 complications.

Complication Severities	30 Days	1 Year	<i>P</i> -value*
	(n=64) N (%)	(n=185) N (%)	
1 (Mild)	32 (50.0)	98 (53.0)	.77
2 (Moderate)	31 (48.4)	75 (40.5)	.31
3 (Severe)	1 (1.56)	12 (6.49)	.19

Table 4: Complication severities for all complications recorded at 30-day and 1-year follow up. Complications reported multiple times by the same patient were recorded, providing they were confirmed to be separate events. Proportions are given as a percentage of all complications recorded in the specified time period. **P*-values are calculated using Fisher’s exact test.

Mortality and PEG Removal

End points for all patients and the dysphagia, head and neck cancer, self/family care and professional care subgroups are given in Table 3.

The 30-day mortality for all patients post-insertion was 4.2% (13 patients), with 10 of these belonging to the dysphagia subgroup. A total of 87 patients (28.4%) died within the first year. The median time to death for the whole cohort was 181 days (IQR 273.5). One patient died less than 7 days post-insertion. At the time of maximal follow up, 75 patients still had their PEG tube in situ. Two patients reported peristomal site pain within 30 days of the removal of their PEG. No other complications were recorded post-PEG-removal.

Comparing the two main indications for PEG, dysphagia and head and neck cancer, 30-day mortality was statistically significantly greater in the dysphagia subgroup compared to the head and neck cancer subgroup ($P=.01$). This was also the case for 1-year mortality ($P=.01$). Patients in the head and neck cancer subgroup were also significantly more likely to have their PEG tube removed within the first year ($P<.001$). The time to death and time to removal were not significantly different between the groups.

1-year mortality was significantly greater in the professional care subgroup than the self/family care subgroup ($P=.004$). Those in the self/family care subgroup were also more likely to have their PEG tube removed in the first year ($P<.001$). No statistically significant difference was found in time to death, time to removal or 30-day mortality.

Discussion

In this longitudinal follow up study of PEG insertion, we have demonstrated a significant cumulative rate of complications over a 1-year period with over 16% of patients being affected in the first 30 days and over 35% being affected by the end of the first year.

There were some interesting variances, namely with head and neck cancer patients being more likely to report peristomal site pain, quicker to report a complication and sooner to require management by members of the secondary care team. We speculate this is likely to reflect their healthier pre-morbid state and subsequently their greater ability to bring attention to symptoms when compared to members of the dysphagia subgroup, who had greater degrees of pre-existing underlying morbidity. Our results for the incidence of pain in the head and neck cancer subgroup were also higher than those reported in the recent literature²⁰.

Historically, guidelines state that late complications are generally avoidable and related to the quality of tube care, although these assumptions are rarely referenced²¹. One might therefore expect a difference in rates or severity of complications between the self/family and professional care groups, but other than pain, this was not apparent. Additionally, no difference was found in the time it took complications to develop between the two groups. Superficially, this suggests that both groups are providing equivalent levels of aftercare, however it is possible that type 1 complications were underestimated for the self/family cohort, as we did not have access to private healthcare company records. Further investigation will be needed to understand this in more depth and education and support interventions should be evaluated for effect on complication rate as a marker of impact.

The 30-day mortality rate is recorded at 4.6% and while this is in keeping with the international literature^{6,11,12}, it marks a significant improvement from the UK National Enquiry report of 2002/3, where 7 day mortality was reported to be as high as 43% (likely attributed to poor patient selection)²². In addition, frequency of early buried bumpers in this cohort within 1 year was low (0.3%). Although reported median time from insertion to development of a buried bumper is 22-35 months, small numbers of early cases are seen and have been reported to be more common with FREKA® PEG²³⁻²⁶.

Patients in the head and neck cancer subgroup were much more likely to have their tube removed within the first year than patients with dysphagia. This is likely as the PEG is inserted prophylactically, and evidence shows the vast majority of head and neck cancer patients do not require PEG feeding after the first year²⁷.

Limitations

Limitations to this study include it being undertaken at a single site and further analysis elsewhere would be useful to replicate the results. In addition, it reports complications with a Freka® CH/FR 15 PEG ENFit® tube only and other brands of tube may result in a different spectrum of complications. We were not able to access the private providers' community notes and therefore it is highly likely we have underestimated the frequency of type 1 complications and that the true rate is higher. Furthermore, due to cumulative mortality or participants no longer requiring a PEG tube the number with full follow up data at 1 year is relatively small.

Conclusion

To conclude, this is the largest study on record following up all complications within 1-year post PEG insertion. PEG insertion is associated with a 16.7% 30-day complication rate, accumulating to 35.6% of the total cohort experiencing at least one complication within one year of insertion. Peristomal pain was the commonest complication and more likely to be reported by those being treated for head and neck cancer. A large majority of complications could be managed in a primary care setting or with secondary care input without requiring admission or invasive management. Support structures and ongoing care are required to assist patients and their carers in enteral tube management to reduce complications and patients should be appropriately counselled about the longer-term impacts prior to insertion.

Statement of Authorship: C. T. Boylan and H. Steed equally contributed to the conception and design of the research, the acquisition, analysis and interpretation of the data, drafting and critical appraisal and revision of the manuscript. D. Barrett, V. Li and S. Merrick all contributed equally to the acquisition, analysis and interpretation of the data and critical

appraisal and revision of the manuscript. All authors gave final approval for the project and agree to be accountable for all aspects of the work, ensuring accuracy and integrity.

Conflicts of interest statement: None declared.

Financial disclosure statement: None declared.

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Figure legend for figure 1:

Figure 1: Flow chart showing flow of participants through the study.

Figure legend for figure 2:

Figure 2: Kaplan-Meier survival functions for patients in the head and neck cancer (blue) and dysphagia (red) subgroups, comparing time to develop any complication, a type 1 complication, a type 2 complication and a type 3 complication. (A) $p=0.042$ (B) $p=0.192$ (C) $p=0.033$ (D) $p=0.869$

Figure legend for figure 3:

Figure 3: Kaplan-Meier survival functions for patients in the self/family care (blue) and professional care (red) subgroups, comparing time to develop any complication, a type 1 complication, a type 2 complication and a type 3 complication. (A) $p=0.125$ (B) $p=0.081$ (C) $p=0.443$ (D) $p=0.074$

**319 participants selected
using inclusion criteria**





