Assessment of complication rates based on time of feeding initiation in radiologically guided gastrostomy tubes: a retrospective study

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PURPOSE
We aimed to assess the association between complication rate and time to feeding in a cohort of patients undergoing radiologically guided placement of gastrostomy tubes.

METHODS
A retrospective study was conducted of all patients receiving pull-type and push-type gastrostomy tubes placed by interventional radiologists between January 1st, 2017 and December 31st, 2018 at a single institution. Primary outcomes included procedural and tube-related complications per medical chart review with a follow-up interval of 30 days. Exclusion criteria were enteral nutrition delayed more than 48 hours, no feeding information, and tubes placed for venting (n=20). Overall, 303 gastrostomy tubes (pull-type, n=184; push-type, n=119) were included. The most common indications for placement included head and neck carcinoma for push-type tubes (n=76, 63.9%) and cerebral vascular accident for pull-type tubes (n=78, 42.4%).

RESULTS
In a multiple regression analysis, there was no statistically significant association between complications and time to feeding ($p = 0.096$), age ($p = 0.758$), gender ($p = 0.127$), indication for tube placement ($p = 0.206$), or type of tube placed ($p = 0.437$). Average time to initiation of enteral nutrition was 12.3 hours for the pull-type and 21.7 hours for the push-type cohort ($p < 0.001$). Additional multiple regression analyses of pull-type tubes and push-type tubes separately also did not find any significant association between complications and the above factors ($p > 0.05$).

CONCLUSION
There was no statistically significant correlation between time to feed and complications, suggesting that there is no clinical difference between early and late feeding following gastrostomy tube placement.

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P ercutaneous radiologic gastrostomy is a well-established safe and effective feeding method (1–5). Early initiation of feeding after tube placement has several benefits, including decreased hospital stay and shorter time on intravenous nutrition, but the theoretical risk of increased complication rate has led many physicians to delay feeding initiation. While several studies have found that early initiation of feeding after tube placement is safe in the endoscopic literature (6–10), the association between time to feed and complications has been less frequently studied in the radiologic literature. Studies that have done so have been limited in the methods of tube placement included, sample size, and types of patients included (11, 12). Furthermore, despite evidence in the endoscopic literature, many physicians do not initiate early feeding after either endoscopic or radiologic gastrostomy placement (13).

Within interventional radiology, the time to initiation of enteric feeding is one variable that remains discrepant between institutions and may pose consequence with respect to complications in the early post-placement setting (6–9, 11, 14, 15). Fora of interventional radiologists have demonstrated physicians are using a wide variety of fasting times following tube placement ranging from "early" (commonly less than 6 hours) to "delayed" (commonly 24 hours or greater) that is neither directly based on evidence nor guideline based (16).

Furthermore, time to feeding following gastrostomy remains an important clinical metric that may impact initiation of therapy, feeding, and hospital discharge. The purpose of this study was to analyze the rate of feeding related complications in a cohort of all patients undergoing either "push" or "pull" type radiologic gastrostomy placement at a single institution based on time to initiation of feeding following tube placement.

Methods

Study design

This was a single-center, retrospective study conducted at a tertiary care academic medical center. The study was approved by the Institutional Review Board under protocol number IRB18-1764, which waived the requirement for informed consent. A code search for all patients who successfully received a gastrostomy tube in the section of interventional radiology between January 2017 and December 2018 was conducted to identify eligible patients (n=348). Patients were required to be at least 18 years of age at the time of tube placement for inclusion. Twenty patients who received tubes for the purpose of venting alone were omitted. An additional 14 patients were excluded because feeding information was not available in their chart due to discharge or absence of documentation of feeding initiation. Eleven patients with time to feed more than 48 hours were excluded, as this does not follow the standard protocol for tube use (Fig.).

In the authors' institution, protocol for suggested time to earliest feeding between pull- and push-type tube placement is different (4 versus 24 hours, respectively), but final determination of initiation of feeding is determined by the patient's primary ser-
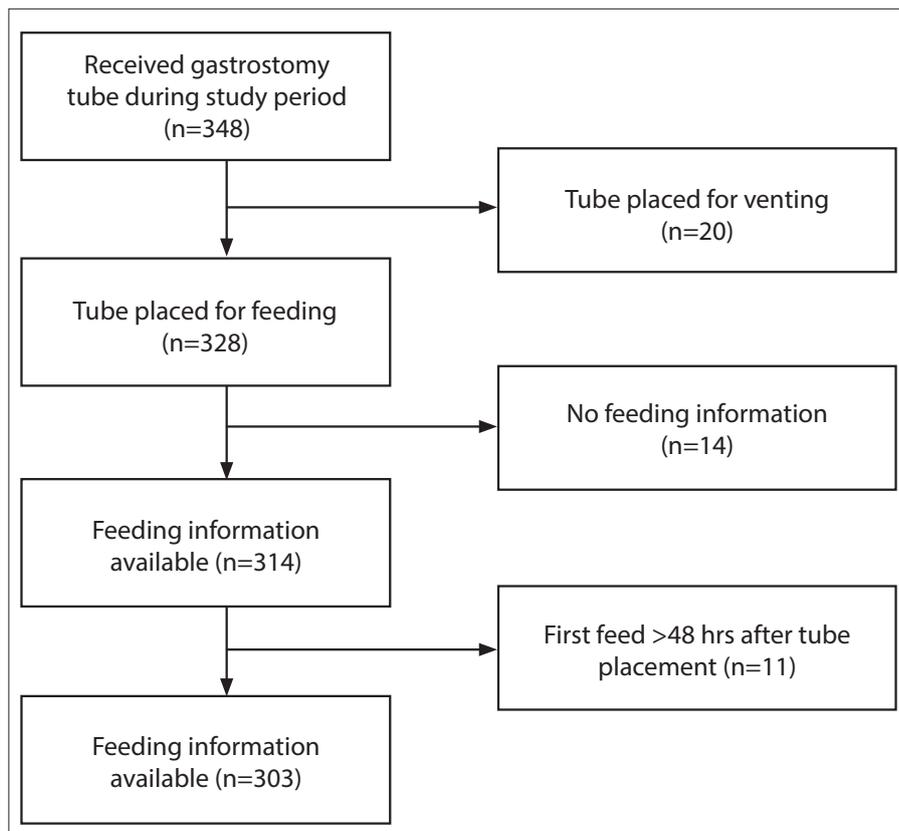

Figure. Patient enrollment.

Main points

- While data suggest the safety of early feeding following endoscopic gastrostomy tube placement, many clinicians delay feeding for all types of gastrostomy placement.

- In this retrospective study of patients who received either push- or pull-type radiologic gastrostomy tube placement, there was no association between feeding time and complications.

- These data suggest that early/late feeding protocols may not make a clinical difference in complication rate.

vice based on patient-specific factors. The primary objective of this study was to identify factors predictive of feeding-related complications, specifically time to feeding. Since early and delayed feeding are often determined by method of tube placement at the study institution, the secondary objective was to compare complications between patients receiving push- and pull-type tubes.

Procedure technique

Push- (balloon retained) and pull-type (mushroom retained) gastrostomy tubes were placed under moderate sedation using previously described techniques (5, 17). Push-type tubes were 16 French. For push-type tubes, three T-fasteners (Halyard type) were used. For pull-type tubes, one T-fastener (Cope type) was used. Contrast verification was used prior to T-fastener release. Pull-type tubes were preferentially placed in all patients unless contraindications (i.e., head and neck or esophageal cancer related obstruction) prohibited placement based on departmental preference. Institutional protocol following gastrostomy placement dictates a specified fasting period in

which feeding is not administered orally or through the enteric tube. For pull-type tubes, this period is designated at minimum 4 hours compared to 24 hours for push-type tubes. When the institution created the protocol, a shorter time to feeding for pull-type tubes was deemed feasible for the purpose of the protocol, given similarity to endoscopic technique (i.e., no over-dilation of the gastrostomy tract during placement and larger mushroom-type retention) and existing literature on endoscopic tubes supporting the safety of early feeding (7, 18).

Data collection

Procedure reports were extracted from the institution's picture archiving and communications system and were reviewed for demographic and procedural information. Type of tube placement (push- or pull-type), general purpose of tube placement (feeding or venting), bumper position, fluoroscopy time, and time of completion of tube placement were identified from the procedural report text. The specific indication for tube placement was also determined from the procedural report text and divided into one of the following categories based on

Society of Interventional Radiology Guidelines (16): cerebrovascular accident, head and neck cancer, other malignancy, other central nervous system, and failure to thrive. When the procedural report did not provide enough information for categorization, the most recent clinical note was used. Electronic medical records were reviewed for time of first feeding, using intake via the gastrostomy tube recorded in patient flowsheets. Despite the presence of an institutional protocol for early (4 hours after tube placement) and delayed feeding (24 hours after tube placement), time to feed was treated as a continuous variable for analysis. Major and minor complications were identified in the electronic medical record using provider notes for the 30 days following tube placement. Feeding related complications were also specifically assessed, including aspiration, peritonitis, tube leakage, and stoma infection as defined in multidisciplinary practice guidelines (16). At the authors' institution, advanced practice nurses follow up with each patient the day following tube placement with a detailed clinical and physical exam. Any additional notes by other providers were also reviewed for the 30 days following tube placement for tube-related complications.

Statistical analysis

Statistical analyses were performed using Stata 16.0 (StataCorp LLC) with level of significance α set at 0.05. Shapiro–Wilk test was performed and demonstrated significant departure from normality for age and feeding time. Two independent groups were compared with Mann–Whitney U test. Three or more independent groups were compared with Kruskal–Wallis test with Dunn multiple comparison post-hoc. Categorical data were compared with Pearson χ^2 or Fisher's exact test. Linear regression was used to evaluate age as related to feeding time. Multiple regression analysis was used to evaluate the primary objective of whether feeding time was correlated with feeding related complications in all gastrostomy placements as well as push- and pull-type gastrostomy placements as subsets.

Results

All gastrostomy tube placements at a single academic center from a two-year period from January 2017 to December 2018 were reviewed. A total of 184 pull-type and 119 push-type gastrostomy placements were included.

Table 1. Time to feeding based on gender, age, and indication			
	Number	Median time to feeding (IQR), hrs	p
Gender			0.344
Female	126	14.0 (5.6–24.9)	
Male	177	17.3 (7.1–23.4)	
Indication			<0.001
CVA	89	9.1 (5.3–22.9)	
Head and neck cancer	81	23.7 (21.3–26.9)	
Other CNS	80	8.8 (5.4–17.6)	
Other malignancy	23	16.3 (6.6–20.8)	
Failure to thrive	24	7.5 (5.0–22.8)	
Replacement	6	3.5 (3.0–4.4)	

There were no significant differences based on gender and age. There was a significant difference between indication for tube placement and time to feed that was found to primarily stem from differences in patients who received gastrostomy for head and neck cancer and other indications (Supplementary Table 1).
IQR, interquartile range; CVA, cerebrovascular accident; CNS, central nervous system.

Median time to feeding was 16.3 hours (interquartile range [IQR], 6.2–23.7 hours).

Median and IQR of time to feeding based on patient demographics is shown in Table 1. In summary, there were no significant differences in time to feeding based on patient demographics. There were differences in time to feed based on indications, which primarily stemmed from differences in patients who received gastrostomy for head and neck cancer and other indications. The Dunn multiple comparison post-hoc analysis also showed that the differences primarily stemmed from differences between head and neck cancer and the other indications (Supplementary Table 1). Median patient age was 66.0 years (IQR, 6.2–23.7 years). There was no significant association between patient age and time to feeding initiation ($p = 0.230$).

Seventy-three patients had feeding initiated "early" (less than six hours) with an average time to feed in this group of 4.05 hours. Seventy-three patients had feeding initiated "late" (more than 24 hours) with an average time to feed in this group of 28.51 hours. There was no statistically significant correlation between occurrence of complications and time to feeding ($p = 0.096$), patient age ($p = 0.758$), gender ($p = 0.127$), indication ($p = 0.206$), bumper position ($p = 0.934$), or fluoroscopy time ($p = 0.577$) in a univariate analysis. Subgroup analyses of only push-type and only pull-type gastrostomy placements also demonstrated no significant correlation between complications and the above factors ($p > 0.05$). Multiple regres-

sion analyses including time to feed, type of tube, and indication also demonstrated no significant correlation between the above factors and occurrence of complications in each of the following groups: all gastrostomy tubes, push-type tubes only, and pull-type tubes only ($p > 0.050$). Table 2 shows the association between complication rate and time to feeding for the push-type only group, pull-type only group, and the combined group in the multiple regression analyses. The complete multiple regression analysis for the full dataset is presented in Supplementary Table 2.

Time to feed as measured by first documented feed was significantly longer following push-type compared to pull-type tube placement (Z= 8.237, $p < 0.001$, Mann–Whitney). Table 3 lists additional comparisons between push- and pull-type tubes.

Overall complication rate was 8.25%. Complications occurred in 6.7% of push-type gastrostomy tube placements compared with 9.2% of pull-type gastrostomy tube placements, which was not significantly different ($p = 0.605$). The proportion of all complications that were major was 12.5% in push-type gastrostomy placements compared with 35.3% in pull-type gastrostomy placements. This difference was not statistically significant ($p = 0.362$) (Table 4).

Twenty patients (15.9% of all patients who underwent push-type gastrostomy tube placement) had feeding initiated earlier than the institution's protocol of 24 hours. One (5%) had a complication, which was peristomal infection.

Table 2. Association between feeding time and complication rate in pull-type, push-type, and both groups

	Number	Median time to feeding (IQR), hrs	p
Pull-type tubes only			
Complication	17	6.9 (5.1–16.1)	0.493
No complication	167	7.7 (5.1–17.9)	
Push-type tubes only			
Complication	8	23.3 (13.5–25.0)	0.493
No complication	111	23.3 (19.3–26.2)	
All tubes			
Complication	25	8.4 (5.1–22.8)	0.096
No complication	278	16.8 (6.6–24.0)	

In multiple regression analyses, there was no statistically significant association between time to feed in either group or when the groups were combined.
IQR, interquartile range.

Table 3. Differences between push- and pull-type tubes

	Push-type	Pull-type	p
Time to first feed (hrs), median (IQR)	23.3 (19.3–26.1)	7.7 (5.1–17.4)	<0.001
Fluoroscopy time (min), mean±SD	4.5±4.22	5.1±4.52	0.322
Bumper position (cm), mean±SD	4.1±1.28	4.0±1.25	0.273

IQR, interquartile range; SD, standard deviation.

Table 4. Complications by push- and pull-type tubes

	Push-type, n (%) (n=119)	Pull-type, n (%) (n=184)	p
Total complications	8 (6.7)	17 (9.2)	0.524
Major complications	1 (12.5)	6 (35.3)	0.362
Minor complications	7 (87.5)	11 (64.7)	

Significance values are from Fisher's exact tests. Minor complications included inadvertent removal (n=9), peristomal infection (n=3), stomal leakage (n=3), buried bumper (n=2), and ileus (n=1). Major complications included aspiration (n=5), peritonitis (n=1), and necrotizing fasciitis (n=1).

Discussion

Time to initiation of feeding following gastrostomy is minimally described in the radiologic literature. Most studies on radiologic gastrostomy describe protocols ranging from "next day" feeding initiation (i.e., 24 hour) up to 3 days following tube placement (19–21). The rationale for delayed feeding is largely borrowed from dated surgical literature, which includes a theoretical risk of aspiration secondary to gastroparesis and paralytic ileus in the post-procedure setting (16). A fasting period of at least 24 hours has thus been previously suggested to restore gastric motility prior to resuming tube feeds (16).

Prospective and randomized controlled trials on percutaneous endoscopic gastrostomy have, however, demonstrated the safety of early gastrostomy feeding dating back to 1986 (7, 18). The observations from these studies suggest that bowel sounds and peristalsis return shortly after gastrostomy insertion, mitigating the risks of increased gastric residuals and aspiration. Similarly, complications from leakage related to an immature (endoscopic) gastrostomy tract have also been shown to be similar in a randomized controlled trial comparing early (3 hour) to delayed (24 hour) feeding protocols (22).

Given that radiologic gastrostomy is similar to endoscopic technique in terms of invasiveness and anesthetic requirements, it stands to reason that early feeding with radiologic gastrostomy should also be safe and effective in terms of timing for initiation of feeding. Sabir et al. (11) investigated the safety of "early" (less than 3 hours) ra-

diologic gastrostomy in outpatient oncology patients, finding that the procedure was well tolerated and eliminated the need for post-procedural hospital admission. While the aforementioned study was important in demonstrating the feasibility of early feeding with radiologic gastrostomy, it was limited by many factors including the lack of a comparator arm, primarily outpatient population, small tube size (12 F), and narrow patient population sample (i.e., oncology patients only).

The current study sought to overcome some of these limitations by including a large number of gastrostomy tubes placed for a variety of indications as well as comparing two types of large bore tubes (push- and pull-types) placed for adult enteric feeding. Additionally, while long-standing feeding protocols are in place at the study institution, the actual time to feeding initiation determined from the medical record varied, allowing for retrospective analysis of time to first feed as a continuous variable, rather than simply as dichotomous early versus late feeding. This study found that there was no significant association between either time to feed or method of tube placement and complication rate in a multiple regression analysis. Time to feed was significantly less in the pull-type group compared to the push-type (21.7 hours [range, 1–48 hours] versus 12.3 hours [range, 1–44 hours]), fitting with the protocol in place at the study institution. The collinearity between time to feed and type of tube placed was also corrected for in the regression model when evaluating the primary outcome. Furthermore, the rates of complications seen across both groups were below the lower threshold limits set by societal guidelines for percutaneous gastrostomy (13%–43%) (16). Additionally, independent multiple regression analyses were performed for only push-type and only pull-type tube placements, and neither analysis showed significant association between complications and time to feeding.

While previous studies have shown that a shorter time to feed was not associated with an increased complication rate, these studies either did not define how time to initiation of feed was measured or primarily determined time to feed based on assumptions that feeds were initiated within a specified protocol (6–12). Therefore, it is unclear when feeds were specifically initiated in these studies. The current study uniquely determined the actual time to

feed based on the first documented feed within the electronic medical record as opposed to assuming strict adherence to protocols. The large range of time to initiation of feeding is due to clinicians' decisions on time of feeding initiation based on patient-specific indications. Despite this, only 23 pull-type tubes (12.5% of total pull-type) had feeding initiation after 24 hours and only 4 (2.1%) before 4 hours. For push-type tubes, only 18 (15.1%) had feeding initiation before 12 hours. Furthermore, when a small cohort of push-type feeding tubes (n=20) were fed "early" out of protocol, the rate of complication was still within the acceptable range (5%). Therefore, while time to initiation of feeding may appear "delayed" in both groups, this study had the advantage of more accurately documenting when feeding was initiated and still found no association between time to feed and complication rate.

This study has some notable limitations, namely those ascribed to single institution retrospective studies. First, although all non-venting patient indications were included, the study institution serves many patients with head and neck cancer for whom push-type gastrostomy was the primary indication. Therefore, the results may not be generally applicable to all patient populations. Second, while earlier feeding with pull-type gastrostomy was demonstrated to be as safe as push-type, the safety and feasibility of early feeding with large bore push-type radiologic gastrostomy was not specifically addressed in the study design. Small subset analysis of this cohort did, however, suggest feeding in this group is safe. Third, as mentioned above, although early (4 hour) feeding was the protocol for pull-type tubes compared with delayed (24 hour) feeding with push-type, the average time to feed within both groups was still greater than 12 hours and demonstrated high variability in timing. This likely reflected practice patterns at the study institution, which places primarily inpatient gastrostomy tubes where initiation of feeding may be influenced by the patient's medical condition and/or comorbidities at time of placement. Additionally, time to feeding was treated as a continuous variable, so the impact of an "early" versus "late" feeding protocol cannot be directly assessed in this study. Although there was no association between time to feed and age or gender, it is possible that clinicians delayed feeding in

patients who they deemed were higher risk for feeding-related complications based on their individual clinical judgment.

In conclusion, this study found no association between time to feeding and complication rate in a large cohort of patients undergoing radiologic guided gastrostomy tube placement for a variety of indications. Therefore, we propose that implementation of an early/late feeding protocol may not make a clinical difference. Furthermore, there was no association between method of tube placement or indication for feeding tube placement and feeding-related complications. While prospective, randomized trials are needed to confirm these findings, the results of this study suggest implementation of an early feeding protocol for radiologically guided push- and pull-type gastrostomy is safely tolerated.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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Supplementary Table 1. Dunn multiple comparison post-hoc analysis: comparison of feeding time by indication category

Indication	Number	Median time to feeding (IQR), hrs
CVA	89	9.1 (5.3–22.9)
Head and neck cancer	81	23.7 (21.3–26.9)
Other CNS	80	8.8 (5.4–17.6)
Other malignancy	23	16.3 (6.6–20.8)
Failure to thrive	24	7.5 (5.0–22.8)
Replacement	6	3.5 (3.0–4.4)

Pairwise Z test statistic	Other malignancy	CVA	Failure to thrive	Replacement	Head and neck cancer
CVA	-0.06 (1.000)				
Failure to thrive	-0.06 (1.000)	-0.00 (1.000)			
Replacement	-0.39 (0.315)	-0.33 (0.505)	-0.33 (0.749)		
Head and neck cancer	0.33 (0.003)	0.39 (0.000)	0.39 (0.000)	0.72 (0.000)	
Other CNS disorder	-0.14 (1.000)	-0.08 (1.000)	-0.08 (1.000)	0.26 (1.000)	-0.47 (0.000)

Each box within this table presents the z test statistic for Dunn multiple comparison post-hoc analysis with *p* value in parentheses. Significant differences did exist between time to initiation of feeding based on indication, which primarily stemmed from differences between head and neck cancer and the other indications.
CVA, cerebrovascular accident; CNS, central nervous system.

Supplementary Table 2. Multiple regression analysis of complications: all tube types included

	Coefficient (95% CI)	SE	T	*p*
Indication	0.021 (0.000 to 0.042)	0.011	1.97	0.050
Age	0.000 (-0.002 to 0.002)	0.001	-0.01	0.990
Gender	0.041 (-0.024 to 0.106)	0.033	1.25	0.214
Type of tube	0.035 (-0.050 to 0.119)	0.042	0.80	0.422
Fluoroscopy time	0.000 (0.000 to 0.000)	0.000	0.64	0.522
Feeding time	-0.078 (-0.164 to 0.008)	0.044	-1.80	0.074
Constant	51.909 (-107.366 to 211.183)	80.932	0.64	0.522

This analysis created the following statistical parameter: $p = 0.171$.
SE, standard error.