

Factors Associated with 30-Day Mortality in Patients after Percutaneous Endoscopic Gastrostomy

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ABSTRACT

Introduction: Percutaneous endoscopic gastrostomy (PEG) is the main accepted method for long-term tube feeding. The aim of this study is to investigate the risk factors associated with early mortality after PEG.

Methods: It is a retrospective survival analysis in a tertiary-level hospital. We reviewed the medical records of 277 patients with PEG placement. The data were analyzed by the Kaplan-Meier method. Multivariable Cox proportional regression models were also built to test the effects of PEG on mortality.

Results: A total of 277 patients who submitted to PEG were studied. One-hundred and sixty (58%) were female, mean age of 73.3 ± 15.7 years. Ninety-three patients (33.6%) had diabetes mellitus and 165 (59.6%) had blood

hypertension. The indications for PEG placement were chronic neurologic dysphagia in 247 (89.5%) patients and tumors and other diseases in 29 (10.5%). The 30 days proportional mortality probability rate was 13%. In a multivariate Cox proportional regression model, preoperative ICU hospitalization (HR 1.79, 95% CI 1.36–2.36, $P=0.000$) and hemoglobin (HR 0.91, 95% CI 0.85–0.98, $P=0.015$) were predictors of early mortality.

Conclusion: In patients who had underwent PEG tube insertion for long-term nutrition, anemia and previous ICU admission were predictors of mortality at four weeks. These factors may guide physicians to discourage the indication for PEG.

Key Words: Deglutition disorders, Malnutrition, Enteral nutrition, Critical illness, PEG tube.

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INTRODUCTION

Percutaneous endoscopic gastrostomy (PEG) has become the mode of choice for long-term enteral feeding over the last decades.¹ Gauderer et al² first reported a PEG tube insertion in pediatric patients with dysphagia but its use has now spread to adults as well. The objective of the procedure is to stabilize and improve the patient's nutritional status and, consequently, their weight.³ Dysphagia due to cerebrovascular disease, oropharyngeal, and esophageal tumors are the most common indications for PEG tube placement.⁴

The PEG tube placement should be performed when the need for enteral nutrition is permanent or longer than six weeks. Life expectancy lower than two months and end-stage chronic diseases are contraindications to the procedure.⁵ Although this procedure is fast and safe, it is not free of complications and is associated with early mortality rates,^{3,6,7} demonstrating the need for a better and objective patient selection criterion to avoid futile indications and wasting resources. Different authors have identified risk factors associated with early mortality, and, thus, it is important to elaborate a clinical protocol to protect

patients who would not benefit from this endoscopic procedure.^{1,3–22}

The aim of the present study is to identify risk factors associated with early mortality in patients availing the PEG insertion to establish a protocol for clinical practices that could help in making decisions regarding undergoing the procedure.

METHODS

Study Design

This is a retrospective study with patients who underwent PEG placement between Jan 2012 and Apr 2019 in a tertiary-care hospital. This hospital is highly certified by the Canadian Council for Health Service Accreditation due to its quality of patient safety, security, and clinical protocols. Furthermore, it has an electronic medical records system certified by the Healthcare Information and Management System Society in its highest level.

Data Collection

Data was collected from adult patients requiring long-term enteral nutrition and submitted to PEG placement for the first time. The exclusion criteria included patients submitted to the PEG replacement, outpatients, patients with incomplete charts, and patients with unsuccessful procedures. PEG placement was indicated by the primary doctor responsible for the patient after a complete assessment of the patient's ability to no longer feed themselves or with help of another person and were dependent of tube feeding. The doctors discussed its risks, complications, and advantages with the patient or with their family, when they could not decide for themselves.

The following variables were collected from the patient's charts: age, gender, main diagnosis (chronic neurologic diseases, tumors, dementia), comorbidities (hypertension, diabetes mellitus, renal disease), laboratory exams (albumin, C-reactive protein, hemoglobin, sodium, potassium, urea), surgical complications, time of survival, and endoscopic report. We considered bleeding, dermatitis, peritonitis, abscess, buried bumper syndrome, and avulsion as surgical complications.

Pre- and postoperative data were also collected: dialysis, orotracheal tube procedure, hospitalization in intensive care unit (ICU). We considered a period of two months before and after the PEG placement.

Surgical Procedure

All procedures were performed by the same surgical team with the support of the anesthesia team. All patients received antibiotic prophylaxis with 2 g of cefazolin unless they were taking antibiotics for other reasons. Sedation was performed with the anesthesiologist's assistance when necessary. The technique described by Gauderer et al² was used to place the PEG tubes using a standard forward-view endoscope (GIFH-180; Olympus America, Center Valley, PA). The procedure was performed in an endoscopy operative room that meets the requirements of the Brazilian legislation. Either a PEG 24 Pull Method Kit (Cook Endoscopy, Indiana, USA) or EndoVive™ enteral access initial placement system (24 Fr Peg-Kit, Boston Scientific, Marlborough, MA, USA) was employed at the team's judgement. Feeding through the tube was partially initiated six hours after the procedure and, after 24 hours, the patients were fed according to the nutrition team. The surgical team conducted follow-up sessions of the patients until their discharge and their caregivers were instructed on how to properly manage the gastrostomy cannula to avoid further complications.

Statistical Analysis

Continuous variables were expressed by the mean ± S.D. and compared by Student's *t* test or median and range and compared with the Mann–Whitney U test. Univariate Cox models were used to identify factors associated with early mortality (four weeks) after the PEG placement. All factors with *P* < .20 after the univariate analysis were

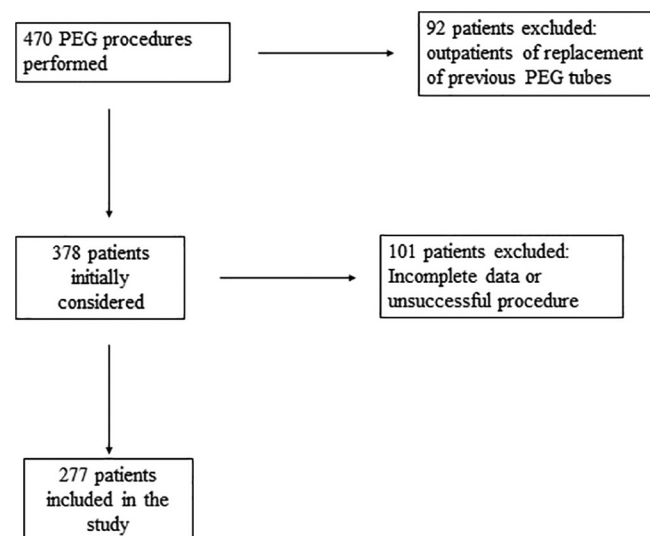


Figure 1. Flowchart of the patients selection.

Table 1.
Patients Characteristics

n (%)	Total (n = 277)	<4 Weeks (n = 36)	>4 Weeks (n = 240)	P
Female	160 (58)	19 (52.8)	141 (58.7)	0.49*
Hypertension	165 (59.6)	21 (58.3)	144 (59.7)	0.87*
Diabetes mellitus	93 (33.6)	8 (22.2)	85 (35.3)	0.12*
Dialysis [§]	13 (4.7)	4 (11.1)	9 (3.7)	0.052*
Orotracheal tube [§]	22 (8)	3 (8.3)	19 (8)	0.93*
ICU hospitalization [§]	175 (63.4)	30 (83.3)	145 (60.4)	0.008*
Tracheostomy [§]	119 (43.1)	19 (52.8)	100 (41.7)	0.209*
Age, years***	73.3 ± 15.7	79.4 ± 14.3	77 ± 16	0.37
Hemoglobin***	10.5 ± 2	9.4 ± 1.7	10.6 ± 2	0.002**
BUN***	58.8 ± 37.8	69.7 ± 36.2	57.1 ± 37.9	0.028**
Albumin (n = 122)***	3 ± 0.5	3 ± 0.6	3 ± 0.5	0.37†
Potassium (n = 223)***	4.3 ± 0.6	4.3 ± 0.6	4.2 ± 0.6	0.47†
CRP (n = 197)***	1464 ± 1464.8	413 ± 1492.2	1639 ± 4241.2	0.21†

* χ^2 , Pearson's test; **, Mann-Whitney U test; ***, mean ± standard deviation; †, Student's *t* test; §, preoperative period; ICU, intensive care unit; CRP, C reactive protein; BUN, blood urea nitrogen.

included in the multivariate model to evaluate their independent effects. A backward stepwise procedure was used for the final Cox model with factors with $P < .05$. In both univariate and multivariate analysis Cox models, the data was reported with hazard ratios (HR) and 95% confidence interval (CI). Proportional mortality curves were plotted as Kaplan-Meier estimates. Two-tailed P values of less than 0.05 were considered statistically significant.

The data was analyzed using the R Project Statistical Computing software version 40.00.1 (www.r-project.org). This study was approved by the Institution Review Board number 662886170.3.0000.5192 and all the Health Insurance Portability and Accountability Act (HIPAA) compliant mechanisms were followed.

RESULTS

Study Population

A total of 277 patients were included in our study (Figure 1), out of which 160 (58%) were female and the mean age was 73.3 ± 15.7 years. Of the total, 93 patients (33.6%) had diabetes mellitus and 165 (59.6%) had blood hypertension. The baseline characteristics of the patients who were submitted to the PEG tube placement are shown in Table 1. The indications for the PEG placement were chronic neurologic dysphagia in 247 (89.5%) patients, and

tumors and other diseases in 29 (10.5%). Two weeks before the procedure, 175 patients (63.4%) were in the Intensive Care Unit (ICU), 119 (43.1%) patients had a tracheostomy, 22 (7.9%) patients had an oro-tracheal tube, and 13 (4.7%) were submitted to dialysis. The differences between groups according to mortality are in Table 1.

PEG-Related Complications

Among the participants, 59 patients had PEG-related complications. Early complications after PEG insertion were: tube avulsion in 35 (12.7%) patients, followed by dermatitis in 13 (4.7%), abscess in six (2.2%), peritonitis in four (1.4%), and bleeding in one (Table 2).

Up to two weeks after the PEG insertion, 119 (43.1%) had been in the ICU, 106 (38.4%) had a tracheostomy tube, 21 (7.6%) underwent dialysis for renal insufficiency, and 14 (5.1%) were intubated (none were reintubations). There was no death related directly to PEG placement and the patients did not need other surgical procedures.

Mortality

The proportional mortality probability at 30 days was 13%. A total of 36 patients died in the time leading up to four weeks (Figure 2).

Table 2.
Clinical Outcomes and Complications of Percutaneous Endoscopic Gastrostomy

n (%)	Total (n = 276)	<4 Weeks (n = 36)	>4 Weeks (n = 240)	P
Dialysis*	21 (7.6)	7 (19.4)	14 (5.8)	0.004
Tracheostomy*	106 (38.4)	20 (55.6)	86 (35.8)	0.023
Orotacheal tube*	14 (5.1)	5 (14)	9 (3.8)	0.01
ICU hospitalization*	119 (43.1)	22 (61.1)	97 (40.4)	0.019
Abscess	6 (2.2)	1 (2.8)	5 (2.1)	0.79
Peritonitis	4 (1.4)	0 (0)	4 (1.7)	0.43
Avulsion	35 (12.7)	3 (8.3)	32 (13.3)	0.40
Dermatitis	13 (4.7)	0 (0.0)	13 (5.4)	0.153
Bleeding	1 (0.4)	0 (0.0)	1 (0.4)	1.000
Buried Bumper syndrome	15 (5.4)	1 (2.78)	14 (5.83)	0.451

*, Postoperative period.

Variables Associated with Mortality up to Four Weeks

Nine preoperative and three postoperative variables that are considered relevant for predicting survival at four weeks were tested using univariate analysis. As shown in **Table 3**, hemoglobin, BUN, and ICU internment were considered significantly associated with mortality up to four weeks. Postoperative dialysis, tracheostomy, and ICU internment were also associated to mortality in four weeks.

Variables Independently Associated with Mortality up to Four Weeks

A multivariate analysis was performed for all variables by the Cox regression. Hemoglobin and preoperative ICU hospitalization were independently associated with mortality up to four weeks by the final model (**Table 4**).

DISCUSSION

Our study demonstrates that low hemoglobin and preoperative ICU hospitalization are factors associated with early mortality in patients submitted to the PEG tube insertion. Moreover, early mortality after the procedure was high (13%), in accordance with the literature, which reports 30-day mortality rates from 1.2 to 32.5%.

Anemia and ICU hospitalization prior to the procedure were independent risk factors for mortality. Our previous study with preliminary data and 150 patients revealed that hemoglobin lower than 10 mg/dL and preoperative ICU

hospitalizations as predictors of mortality in eight weeks.²³ This was the first study to demonstrate these factors as predictors, but we did not have a proper sample to evaluate mortality in four weeks at the time. The present study with almost double the patients allowed us to properly evaluate four-week mortality leading us to confirm that the same factors were associated with mortality.

Various studies have investigated factors with the risk of 30-day mortality in different populations. However, many did not exhibit an adequate mathematical analysis, and they identified heterogeneous factors that are grouped in two big categories: factors associated with chronic diseases and factors associated with advanced signs of malnutrition

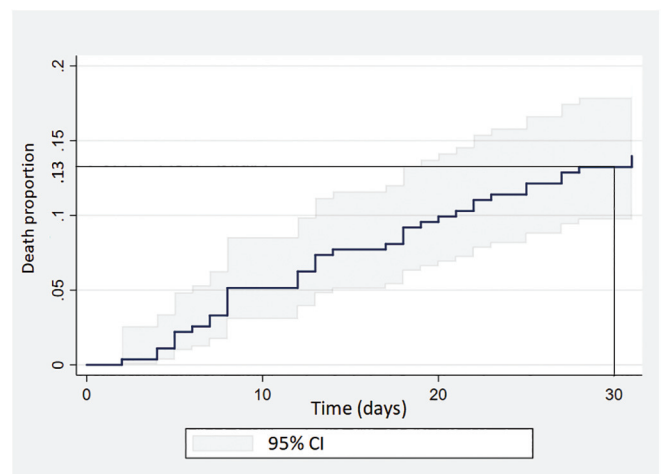


Figure 2. Kaplan-Meier graph showing four-week mortality.

Table 3.
Univariate Analysis of Factors Associated with Survival at Four Weeks

Variables	HR (CI 95%)	P
Preoperative dialysis	1.33 (0.4–3.9)	0.598
Preoperative ICU hospitalization	2 (1.5–2.6)	<0.001
Preoperative endotracheal intubation	1.05 (0.3–3.5)	0.930
Preoperative tracheostomy	1.06 (0.5–2.07)	0.848
Hemoglobin	0.9 (0.8–0.9)	<0.001
BUN	1.005 (1.002–1.008)	<0.001
Albumin	1.09 (0.5–2.3)	0.801
Potassium	0.99 (0.6–1.6)	0.996
CRP	1.00 (0.99–1.00)	0.692
Postoperative dialysis	3.11 (1.9–4.9)	<0.001
Postoperative ICU hospitalization	1.6 (1.3–2.1)	<0.001
Postoperative tracheostomy	1.7 (1.3–2.2)	<0.001

HR, hazard Ratio; BUN, blood urea nitrogen; CRP, C reactive protein; ICU, intensive care unit.

(hypoalbuminemia, anemia). Laboratory parameters such as serum albumin, C-reactive protein, serum sodium, BUN, and neutrophils were independently associated with mortality.^{4,13–18,20,21} Our previous study was the only one to discover low hemoglobin as a predictor of mortality. Age and malignancy were also risk factors described by some authors.^{3,5,16,19,21} Our sample was not enough to accurately study the effects of serum albumin, serum sodium, and C-reactive protein in early mortality due to the absence of these values in many patients: chiefly albumin and C-reactive protein.

Other authors reported early mortality after PEG but with no associated factors.^{24–29} In our cohort, surgical complications

from the procedure were not predictors of mortality. Oh et al²⁴ evaluated 116 patients with only three deaths (2.6%) in 30 days. PEG-related complications and mortality were not increased in the elderly group (≥ 65 years old) when compared to younger patients. Logistic regression in their cohort did not find any factor independently associated with mortality. Wirth et al⁹ performed a prospective multicenter observational study with 197 patients, where dysphagia and insufficient food intake were the main indications for PEG insertion and 9.6% of the patients had severe complication after the procedure. Mortality was higher in patients with severe complications caused by the procedures, such as peritonitis and severe wound infections.

Table 4.
Results of the Adjustments of the Initial and Final Cox Regression Models to Identify Risk Factors for Mortality of PEG in Patients

Variables	Initial Model		Final Model	
	HR (CI 95%)	P	HR (CI 95%)	P
Postoperative dialysis	2.74 (1.7–4.45)	<0.001	3.06 (1.91–4.89)	<0.001
Preoperative ICU hospitalization	1.7 (1.25–2.3)	0.001	1.79 (1.36–2.36)	<0.001
Postoperative ICU hospitalization	1.14 (0.86–1.51)	0.342		
Postoperative tracheostomy	1.39 (1.07–1.82)	0.013	1.45 (1.11–1.88)	0.005
Hemoglobin	0.92 (0.86–0.99)	0.041	0.91 (0.85–0.98)	0.015
BUN	1 (0.99–1.00)	0.127		

BUN, blood urea nitrogen; ICU, intensive care unit; HR, hazard ratio.

Our study had no deaths from complications after the PEG placement. Despite the fact that these factors cannot be evaluated before the procedure, they were not associated with mortality. In our multivariate analysis, postoperative tracheostomy and dialysis were also independently associated with mortality. It was also found that patients who submitted to these interventions had higher risks of mortality. However, these factors can only be identified after the PEG placement and cannot aid in determining which patient would benefit from the surgical procedure.

The Timing to PEG

The European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines for the PEG tube placement states that its indication should not be a terminal measure in patients with short life expectancy or advanced dementia.³⁰ The European Society of Gastrointestinal Endoscopy (ESGE) also recommends refraining from PEG placement in patients with a life expectancy shorter than 30 days.³¹ Furthermore, it is important to select patients properly based on medical and ethical indications. Older patients with severe comorbidities have lower quality of life after the PEG insertion. Despite the plurality of parameters and variables associated with early mortality found described in the literature, the problem may be the timing when the procedure is indicated. An early indication prior to weight loss and catabolism may benefit patients as suggested by Dietrich and colleagues.³² The ESGE guidelines (2021) also recommends early PEG tubes in some patients with chronic degenerative diseases or some types of malignancy if patients present weight loss despite of oral nutrition.³¹ Performing the procedure when the patient is already malnourished and suffering from an advanced disease may be a severe mistake, contributing to early mortality. Studies have showed that increased levels of albumin are associated with longer survival.^{13–16} In our study, patients with anemia or those who had been in the ICU before the procedure were not in their best nutritional status when evaluated for the PEG insertion. The same might have happened in other cohorts with patients with low serum albumin, malignancy, and elevated inflammatory markers such as the C-reactive protein.

Strengths and Limitations

This study has several limitations. First, it is a retrospective cohort study with no comparison group. We could not evaluate all the data we wanted due to the lack of information in the medical records. Hospitalized patients have a higher risk of death after the PEG tube placement and our cohort was composed solely of these patients. Our study does not consider the locoregional characteristics of the population and

as such, adds to the limitation of the analysis. Many patients were tended to at home with inadequate care for certain types of complications. Therefore, we cannot provide an external validation of our results. The strength of this study lies in our sample, the numbers of which practically doubled from our previous study. This larger sample with increased power could proportionate more reliable results.

CONCLUSION

In conclusion, our study discovered that anemia and previous ICU admission were predictors of mortality at four weeks after the percutaneous endoscopic gastrostomy insertion. These factors may guide physicians to discourage the indication for PEG. The indication for the PEG tube should be rigidly assessed in patients who are either in the ICU and suffer from low hemoglobin levels. It is of utmost importance that a protocol must be developed to address all patients who should benefit from the procedure based on their baseline characteristics.

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