

Predicting outcomes and complications of percutaneous endoscopic gastrostomy

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Background and study aims: Percutaneous endoscopic gastrostomy (PEG) is the preferred route for long-term enteral feeding. Our aims were to prospectively evaluate the outcome (“PEG status”) and complications of PEG and to determine whether these can be predicted by patients' baseline characteristics.

Patients and methods: We conducted a prospective study in two tertiary hospitals between August 2003 and January 2005, enrolling all patients who were undergoing PEG placement. We completed a questionnaire with details of demographic data, diagnosis, indication for PEG, Charlson's co-morbidity index, Barthel's index, laboratory tests, complications, and date and cause of death. Patients were followed at scheduled appointments. Univariate and multivariate analyses were performed.

Results: 168 patients (48% male, 52% female; mean age \pm standard deviation 74 ± 16 years) underwent PEG using the pull technique. The main indication was neurogenic dysphagia (156 pa-

tients, 92.9%). Although most indications were appropriate, in half the cases these were established too late. There were no procedure-related deaths. Major complications occurred in four patients (2.4%); minor complications occurred in 52 patients (31%). No single variable could predict complications. Fifteen patients (9%) had the PEG removed. No single variable was independently associated with PEG removal. The mortality was 6.5% at 30 days, 17.3% at 90 days and 33.9% at 1 year. The C-reactive protein was the only predictive factor of early mortality (≤ 30 days), and Charlson's co-morbidity index was the only predictive factor of late mortality (> 30 days).

Conclusions: PEG placement is an easy and safe procedure, although it is often requested too late. No single variable could predict complications or PEG removal. C-reactive protein was found to be predictive of early mortality and Charlson's index was predictive of late mortality.

Introduction

Obtaining enteral access has become the foundation of aggressive nutritional support. Since it was first described in 1980, percutaneous endoscopic gastrostomy (PEG) has been the preferred route for long-term enteral feeding of patients whose gastrointestinal tract is functionally intact but who are unable to maintain sufficient oral intake as a result of a variety of medical conditions [1–3]. The most common indication is inadequate swallowing because of a neurological event or secondary to oropharyngeal cancer. We can also use PEG for gastric decompression or nutritional supplementation in patients who are undergoing radiotherapy or chemotherapy. A number of advantages have been claimed for PEG in comparison with nasogastric or orogastric tubes, such as greater comfort, less frequent displace-

ment, greater improvement in nutritional status, and a better cosmetic appearance [3]. Feeding via PEG should be the preferred method if the patient's nutritional intake is likely to be inadequate for a period exceeding 2–4 weeks [1,3]. PEG placement is considered to be an easy procedure, with a success rate of more than 95% [4]. However, there have been very few prospective studies evaluating the outcomes of PEG [5–8]. Kobayashi et al. [6] reported a 7-day mortality of 4% and a 30-day mortality of 20%. A high long-term (1-year) mortality of more than 60% has also been reported [5,8]. Minor complications were reported to occur more often (13%–20%) and included peristomal wound infection, tube disintegration, clogging, and leakage, and ileus [7,8]. Major complications occurred infrequently (3%–4%) and included aspiration, peritonitis, premature removal, tumor implantation, buried

bumper syndrome, gastrocolocutaneous fistulas, necrotizing fasciitis, and hemorrhage.

Patients receiving a PEG are usually seriously ill, often with major neurological disabilities. The outcome after PEG insertion is variable. Some studies identified that older patients, those with co-morbidity, and severely ill patients had the poorest survival rates [6,9]. Conversely, younger patients and/or those with a diagnosis of localized head and neck cancer are more likely to be able to have the PEG removed and resume oral nutrition [10].

The aims of this study were to prospectively evaluate the outcome ("PEG status") and complications of PEG and to determine whether these can be predicted by patients' baseline characteristics.

Patients and methods



This was a prospective study, and all consecutive patients scheduled for PEG placement were enrolled. All the procedures were performed by the same endoscopic team at two tertiary general hospitals in Rio de Janeiro, Brazil (the Copa D'Ór and Quinta D'Ór hospitals), between August 2003 and January 2005. PEG placement was requested by the patients' primary physicians and no patient was denied the procedure. Written informed consent was obtained from the patient or from a close family member. This study was approved by the Ethics Committees of both hospitals.

We excluded patients in whom the PEG placement could not be performed for technical reasons or because of severe coagulation disorders, and patients who declined to participate in the study. We collected demographic data, and information on the primary diagnosis, the indication for PEG, and the medical history, and recorded the Charlson co-morbidity index, the Barthel index, and the results of laboratory tests (hemoglobin, albumin, creatinine, C-reactive protein [CRP]) before PEG placement.

Charlson's co-morbidity index is a validated, weighted index of co-morbid conditions that has been used to predict mortality. The Charlson co-morbidity index takes into account the number and the seriousness of co-morbid diseases [11]. It takes into account 15 diseases and assigns different weights to each disease: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, mild liver disease, and diabetes all score 1 point; diabetes with end-organ damage, hemiplegia, and moderate or severe renal disease all score 2 points; moderate or severe liver disease score 3 points; and AIDS scores 6 points. The risk of death increases as the number of associated diseases increases. Charlson et al. [11] reported the percentage of patients who died of co-morbid disease for the different scores: 8% for a score of 0, 25% for a score of 1, 48% for a score of 2, and 59% for scores of 3 or more. This system has been validated in Brazil and has been correlated with hospital mortality figures [12,13].

Barthel's index is a functional scoring system that specifically measures the degree of assistance required by a patient. This index contains ten items of varying weights and scores activities of daily living [14]: bathing and grooming both score 0 or 5 points; feeding, dressing, bladder control, bowel control, getting onto or off the toilet, and ascending and descending stairs all score 0, 5, or 10 points; movement from wheelchair to bed and walking on a level surface both score 0, 5, 10, or 15 points. The total Barthel index is a cumulative score of the ten items, with a maximum

score of 100 points corresponding to complete independence, and a minimum score of 0 points corresponding to total dependence. The Barthel index cutoff scores are defined as an index of 45–100 points for a favorable outcome and an index of less than 45 for an unfavorable outcome [15].

Each case was reviewed by the endoscopic team and an independent determination of the appropriateness of PEG placement was made. PEG placement was considered to be appropriate when the patient had a functionally intact gastrointestinal tract but was predicted to be unable to resume oral ingestion for 30 days [1]. The indications included neurogenic dysphagia without obstruction, obstruction due to head and neck tumor or trauma, and the need for gastric decompression and supplemental nutrition for patients who were undergoing chemotherapy or radiation therapy [16]. Requests for PEG were considered "appropriate and timely" when made within 1 month of enteral tube feeding and "appropriate but late" when made after more than 1 month of enteral tube feeding, in accordance with the latest guidelines [1,3]; other requests were considered "inappropriate."

Conscious sedation was administered using a combination of intravenous midazolam and meperidine in all suitable patients. At our institutions, PEG tubes are placed using the "pull" technique. They are inserted as previously described by Gauderer et al. [2]. We used the same PEG kit (PEG-24; Wilson-Cook, Winston-Salem, North Carolina, USA) for all patients. Patients who were on antibiotic treatment for various infections at the time of PEG placement were maintained on their regimens. Patients who were not being treated for infection received prophylaxis with an antibiotic suggested by the bacteriological profile of their unit. It was possible to commence feeding through the PEG tube 2 hours after the procedure.

Patients were followed by the endoscopic team at scheduled intervals (on days 1, 2, 7, 15, 30, 90, 180, and 360 after PEG placement), until either the PEG was removed or the patient died. The data we collected included information on any complications of PEG, the status of the PEG, and mortality and its cause. Patients were seen personally or were contacted by telephone after being discharged to provide details regarding complications and follow-up. During patient examinations the endoscopic team inspected the PEG site personally.

Complications were divided into early (occurring within 30 days after PEG placement) and late (occurring after 30 days). Complications were further subdivided into major and minor categories. Major adverse events were defined as those requiring surgery, causing permanent adverse sequelae, or resulting in death. Minor adverse events were defined as those requiring either minor or no treatment and resulting in no permanent sequelae.

Statistical analysis

The study was designed in relation to a type I error of 0.05 and a type II error of 0.20, so the sample size required was calculated to be 98 patients. SPSS (SPSS Inc., Chicago, Illinois, USA) was used to analyze the data. Univariate analysis was performed using chi-squared tests and Student's *t*-test. To identify factors that independently predict the various outcomes, multiple logistic regression analysis was applied. Survival curves were plotted as Kaplan–Meyer estimates and compared by means of the log-rank test. In addition, the Cox proportional hazard model was used to account for possible effects of other variables on survival. Two-tailed *P* values of less than 0.05 were considered to be statistically significant.

Results



A total of 170 patients were scheduled to undergo PEG. Two patients were excluded because a lack of lighting precluded PEG insertion. Therefore 168 patients were included in the study. The mean age \pm standard deviation (SD) of included patients was 74 ± 16 years (range 11–100), 52.7% of the patients were female, and 52% of the patients came from the Copa D'Or Hospital.

The predominant indication was neurogenic dysphagia without obstruction ($n = 156$, 92.9%), followed by head and neck tumor or trauma ($n = 9$, 5.4%), nutritional supplementation ($n = 2$, 1.2%), and gastric decompression ($n = 1$, 0.6%). We considered 98.8% of referrals to be appropriate, but half of these were made later than would be ideal (77 patients had had a nasogastric tube in situ for more than 1 month despite having an indication for PEG). The most common underlying diagnoses were cerebrovascular accident ($n = 43$, 28%), dementia ($n = 23$, 15%), Parkinson's disease ($n = 19$, 12%), hypoxic-ischemic brain injury ($n = 7$, 11%), and cerebral tumor ($n = 10$, 6%). The mean \pm SD Charlson score was 3.4 ± 2.2 (with a median score of 3) and ranged from 0 to 11. The mean \pm SD Barthel score was 6 ± 17 (with a median score of 0) and ranged from 0 to 100.

The mean dose of midazolam used was 3 ± 2 mg (median dose 3 mg, range 0–10 mg). The mean dose of meperidine used was 11 ± 20 mg (median dose 0 mg, range 0–100 mg). No procedure-related deaths occurred.

The mean follow-up period was 156 ± 134 days (median 116 days). Three patients were lost from follow-up after being discharged from hospital. **Table 1** summarizes the clinical and laboratory characteristics of the patients who were undergoing PEG, according to their final status.

Complications

Major complications affected four patients (2.4%) (**Table 2**). The only major early complication occurred in a 60-year-old man who had a tube loss with an immature tract 22 days after PEG placement. He developed peritonitis and underwent an exploratory laparotomy, but died.

The first late major complication occurred in an 87-year-old man in whom the first 6 months after PEG placement had passed uneventfully. At 6 months, however, the tube came out and a tube change was performed in the emergency room. The stomach de-

Table 2 Major and minor complications of PEG placement

Major complications (n)	Minor complications (n)
Inadvertent tube loss followed by peritonitis (2)	Leakage of gastric juice (21)
Buried bumper syndrome with cellulitis (1)	Minor peristomal infections (15)
Gastrocutaneous fistula (1)	Inadvertent tube loss (11)
	Skin erythema (11)
	Buried bumper syndrome (10)
	Minor orificial bleeding (5)
	Local pain (1)
	Gastrointestinal bleeding from PEG site ulcer (1)

tached itself from the abdominal wall and he developed peritonitis. He was admitted for an exploratory laparotomy but died. The second major late complication occurred in a 74-year-old woman who developed constant leakage of gastric juice 3 months after PEG placement. The tube was removed, but she developed gastrocutaneous fistula, which did not close despite all the measures we tried. She died as a result of her neck tumor and with open fistula. The last major late complication occurred in an 80-year-old woman who developed buried bumper syndrome 6 months after the PEG placement, which was followed by extensive cellulitis of the anterior abdominal wall. The tube was removed and treatment with intravenous antibiotics instituted. She needed two plastic surgery operations to reconstruct the abdominal wall.

Minor complications occurred during follow-up in 52 patients (31%) (**Table 2**). Of these, 44% occurred during the first 30 days after PEG placement. These included minor peristomal infections ($n = 9$, 5.4%), which were treated with local measures plus antibiotics; minor orificial bleeding ($n = 4$, 2.4%), which did not require intervention; leakage of gastric juice ($n = 4$, 2.4%), which resolved with local care; skin erythema ($n = 3$, 1.8%), which resolved with local treatment and without antibiotics; local pain ($n = 1$, 0.6%), which resolved with analgesics; and inadvertent removal of the tube ($n = 1$, 0.6%), which was replaced manually and immediately by a healthcare provider.

Minor late complications included leakage of gastric juice ($n = 17$, 11.2%), inadvertent removal of the PEG tube ($n = 10$,

Table 1 Clinical and laboratory characteristics of patients undergoing percutaneous endoscopic gastrostomy (PEG) placement, with respect to the final PEG status/outcome

	All patients n = 165**	Final outcome		
		Died n = 56	PEG in place n = 94	PEG removed n = 15
Sex, female/male	87/78	39/17	40/54	8/7
Mean \pm SD age (range), years	74 ± 16 (11–100)	77 ± 11 (52–93)	74 ± 18 (11–100)	64 ± 19 (20–81)
Mean \pm SD follow-up (median), days	153 ± 135 (115)	112 ± 102 (80)	185 ± 145 (150)	136 ± 132 (106)
Indication*, 1/2/3/4	153/9/1/2	51/4/0/1	91/2/0/1	11/3/1/0
Mean \pm SD Charlson index (median)	3.4 ± 2.2 (3)	4.1 ± 2.4 (4)	3 ± 2 (3)	2.5 ± 1.8 (3)
Mean \pm SD Barthel index (median)	6 ± 17 (0)	6.4 ± 20 (0)	3.8 ± 9 (0)	19 ± 32 (5)
Mean \pm SD albumin (median), g/dL	2.6 ± 0.5 (2.6)	2.6 ± 0.5 (2.7)	2.6 ± 0.4 (2.6)	2.9 ± 0.6 (2.6)
Mean \pm SD creatinine (median), mg/dL	0.8 ± 0.4 (0.7)	1 ± 0.1 (0.8)	0.7 ± 0.3 (0.7)	0.8 ± 0.2 (0.7)
Mean \pm SD CRP (median), mg/dL	5 ± 7 (2.9)	6 ± 6 (3.9)	4 ± 7 (2.6)	5 ± 5 (3.8)
Hematocrit	32 ± 4 (32)	31 ± 4 (30)	33 ± 4 (33)	34 ± 4 (34)

CRP, C-reactive protein; SD, standard deviation.

* Indications for PEG: 1 = neurogenic dysphagia, 2 = head and neck tumor or trauma, 3 = gastric decompression, 4 = nutritional supplementation.

** Three patients were lost from follow-up.

6.0%), buried bumper syndrome ($n = 10$, 6.0%), skin erythema ($n = 8$, 4.8%), minor peristomal infections ($n = 6$, 3.6%), minor bleeding ($n = 1$, 0.6%), and gastrointestinal hemorrhage caused by an ulcer in the PEG site ($n = 1$, 0.6%). These complications all resolved with conservative treatment.

No single variable was found to be associated with complications.

Patient and clinical characteristics and PEG outcome

Only 15 patients (9%) had the PEG removed and resumed oral nutrition. In comparison with the patients who were not able to have their PEG removed, these patients were younger (64 ± 19 years vs. 75 ± 18 years, $P = 0.01$), they had higher mean \pm SD Barthel index scores (19 ± 32 vs. 5 ± 14 , $P = 0.002$), and they had higher mean \pm SD albumin levels (2.9 ± 0.6 g/dL vs. 2.6 ± 0.4 g/dL, $P = 0.04$). Multiple logistic regression analysis showed that no single variable was independently associated with PEG removal.

Eleven patients (6.5%) died in the first 30 days after PEG placement. These patients had a higher mean \pm SD Charlson index score (5.5 ± 2.4 vs. 3.2 ± 2.1 , $P = 0.001$), a higher mean \pm SD CRP level (10.1 ± 3.8 mg/dL vs. 4.6 ± 0.5 mg/dL, $P = 0.02$) and a higher mean \pm SD creatinine level (1.1 ± 0.7 mg/dL vs. 0.8 ± 0.4 mg/dL, $P = 0.05$). The CRP was the only variable that was independently associated with the 30-day mortality (see **Table 3**). The survival in patients with a CRP level of > 5 mg/dL was significantly lower ($P = 0.01$, log-rank test) (**Figure 1**).

A total of 29 patients (17.3%) died in the first 90 days after PEG placement. These patients had a higher mean \pm SD Charlson index score (4.8 ± 2.6 vs. 3.1 ± 2.0 , $P < 0.001$), a higher mean \pm SD creatinine level (1.0 ± 0.7 mg/dL vs. 0.8 ± 0.3 mg/dL, $P = 0.008$), and showed a male preponderance (72% vs. 47%, $P = 0.02$). The Charlson score was the only variable that was found to be independently associated with the 90-day mortality (**Table 3**).

Altogether, 56 patients (33.9%) died in the first year after PEG placement. These patients were older (77 ± 11 years vs. 73 ± 18 years, $P = 0.03$), had a higher mean \pm SD Charlson index score (4.1 ± 2.4 vs. 3.0 ± 1.9 , $P = 0.002$), a lower mean \pm SD hematocrit (31 ± 4 vs. 33 ± 4 , $P = 0.006$), a higher mean \pm SD creatinine level (1.0 ± 0.6 mg/dL vs. 0.7 ± 0.3 mg/dL, $P = 0.001$), and showed a male preponderance (70% vs. 43%, $P = 0.002$). The Charlson index score was the only variable that was found to be independently associated with the 1-year mortality (**Table 3**). The mean \pm SD survival in patients with a Charlson co-morbidity index of ≤ 4 was 358 ± 23 days, compared with a mean \pm SD survival in patients with a Charlson co-morbidity index of > 4 of 263 ± 36 days ($P = 0.02$, log-rank test) (**Figure 2**).

Discussion

Our study is one of only a few studies that have prospectively followed patients after PEG placement. It confirmed the high

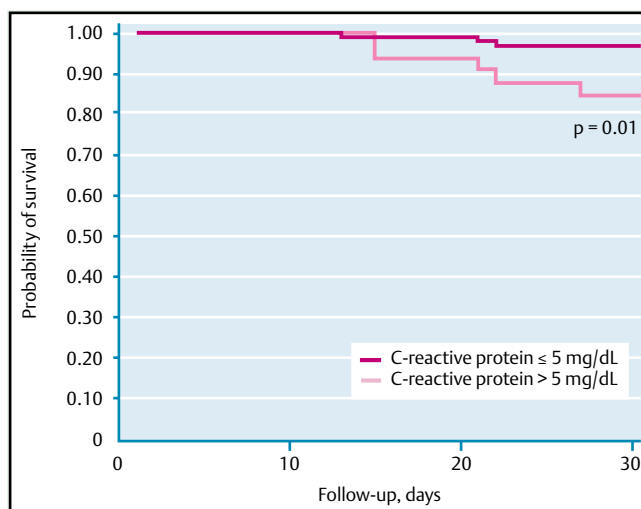


Figure 1 Kaplan–Meier survival curves after percutaneous endoscopic gastrostomy (PEG) placement, according to the C-reactive protein level. The P value was calculated using the log-rank test.

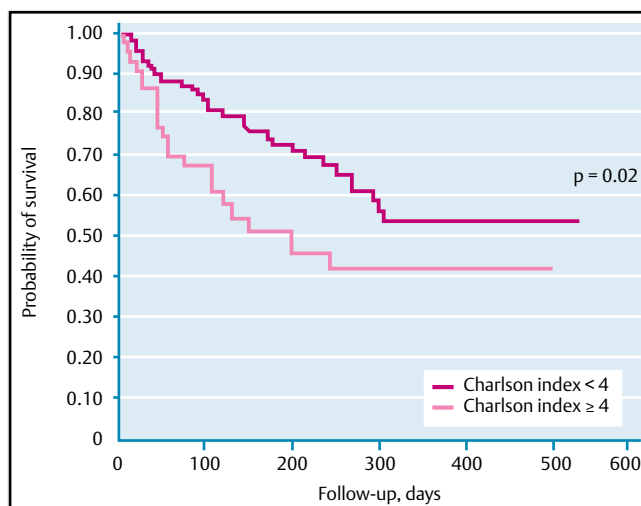


Figure 2 Kaplan–Meier survival curves after PEG placement, according to the Charlson co-morbidity index. The P value was calculated using the log-rank test.

success rate of PEG placement and its low procedure-related mortality. This study highlighted two clinical factors that were related to higher mortality: PEG placement in the setting of an acute illness or co-morbidity. Both the indicators for these factors, the Charlson co-morbidity index and the CRP, can be readily used in day-to-day clinical practice, and could assist physicians in the difficult PEG-placement decision process.

We performed 168 procedures in about 18 months. Although the great majority of referrals were considered to be appropriate, the endoscopic team considered that half of them were made too

Outcome	Rate	Variable	Hazard ratio	as % confidence interval	P
30-day mortality	6.5%	C-reactive protein	1.054	1.007–1.102	0.02
90-day mortality	17.3%	Charlson index	1.282	1.099–1.496	0.002
1-year mortality	33.9%	Charlson index	1.220	1.072–1.389	0.003

Table 3 Results of the Cox regression analysis that was performed to assess the effect of independent variables on survival

late. Because we deal mainly with older patients, most of whom have a neurological type of dysphagia and severe co-morbidities, we decided to choose 30 days as the limit for enteral-tube feeding. Many of our patients were in a permanent vegetative state and had had a nasoenteral tube in place for much longer than 1 month before the PEG was requested. This profile was reflected by the low Barthel index found within this population. Depending on the duration of the dysphagia and the neurological deficit, severe nutritional deficits were observed at the start of the study. Nowadays, an important purpose of PEG should be to diminish or prevent the development of malnutrition rather than just the treatment of severe cases. PEG placement should therefore be considered much earlier and more frequently in appropriate patients. As well as appreciating the ethical issues that are associated with PEG, primary physicians need to be much better informed about the appropriate time for requesting PEG placement. Many other authors have shifted toward earlier consideration of feeding via PEG tube in appropriate patients [3]. PEG placement is a safe procedure. There were no procedure-related deaths. Only two patients died as a consequence of inadvertent PEG tube removal. Their poor nutritional status could be one of the explanations why they still had an immature tract 22 days and 6 months after PEG insertion. All minor complications were easily managed and did not seriously affect the patient. The rates of 2.4% for major complications and 31% for minor complications are acceptable. In recent studies, minor complication rates of 5%–50% and major complication rates of 0.3%–8% have been reported [7,17–19]. Most of the available data on complications have come from retrospective studies. This prospective study emphasizes that complications do still occur despite close follow-up. We believe that a specialized, team-oriented, and active approach during follow-up is important in order to identify some complications early and perhaps to avoid major complications.

One of the benefits of PEG is that it can provide temporary support for patients who are expected to resume oral nutrition. According to Naik et al. [10], the following factors are potential predictors of PEG removal: age < 65 years, head and neck cancer, albumin > 3.75 g/dL, and serum creatinine < 1.1 mg/dL. Although there were statistically significant differences in age, Barthel index, and albumin levels, it was impossible to predict PEG removal in our population. Our patients were older, and more of them had a neurological type of dysphagia and severe co-morbidities, compared with the patients in the study by Naik et al. [10]. Similar to our experience, Kobayashi et al. [6] demonstrated that no patient with dementia resumed adequate oral intake.

Our median Charlson index score of 3 anticipated high mortality. Most of our patients were older and had chronic and degenerative diseases. Although the mortality in our study was substantial, it compared favorably with the mortality reported in other studies [5,6,8,19–21]. One of the explanations for this difference is the higher percentage of patients with neoplastic disease in these other series in comparison with our population.

Janes et al. [20] identified albumin and co-morbid disease as independent predictors of 30-day mortality. In our study, CRP was the only variable independently associated with 30-day mortality. Some patients with elevated CRP levels were receiving antibiotics for the treatment of infection. However, we only performed PEG placement in stable patients who had had at least 5 days of antibiotic therapy and no fever. In addition, all the deaths occurred more than 10 days after PEG placement. The CRP is useful for predicting the short-term risk of death and can probably

identify the presence of acute conditions that could adversely affect the patient outcome. Perhaps PEG placement ought to be postponed in patients with any acute illness.

Factors related to medical and nutritional condition, such as age, co-morbidities, and abnormal laboratory parameters can affect the outcome. However, acute disease processes that can increase the CRP were most important in the early period and co-morbid diseases were responsible for late mortality. We considered the lack of association of all other variables and outcomes as a true fact. Post-hoc statistical power calculation demonstrates an even higher statistical power than that used to calculate the sample size. The identified predictive factors might be able to guide the decision-making process, especially in cases where the risk–benefit relationship is not clear-cut.

Many factors have to be considered before coming to a final decision on PEG placement, such as the primary disease process and the likelihood of recovery, the presence of co-morbid diseases and their severity, the possibility of any acute illness, societal values, the wishes of the patient, institutional factors (e.g. staffing levels, availability of supervision), and the ability of the family and other care-givers to care for the patient. It is practically impossible to transform this complex decision-making process into an objective one. However, we should try to establish better and more objective patient selection criteria for PEG placement. Our study is one of only a few studies that have prospectively followed patients after PEG placement. It suggests that Charlson's co-morbidity index and the CRP, two indicators that could be easily measured and applied in clinical practice, might be able to assist the physician in making these difficult decisions.

We have to try to establish strategies for using our findings in a clinical setting. Charlson's co-morbidity index could be used to select the patients with a higher risk of mortality independent of the PEG placement itself. However, although it provides important information, we should not deny patients the procedure solely on the basis of this index. Conversely, the CRP might be useful as an indicator that the procedure should be postponed for a few days until acute illness is under control.

In conclusion, PEG placement is an easy and safe procedure, although we felt that it was requested too late in almost half of our patients. The procedure was associated with a major complication rate of 2.4% and a minor complication rate of 31%. Fifteen patients (9%) eventually had their PEG removed. No single variable could predict the development of complications or the resumption of oral nutrition. We had no procedure-related mortality, our 30-day mortality was 6.5%, our 90-day mortality was 17.3%, and our 1-year mortality was 33.9%. The CRP level was the only predictive factor for early mortality and the Charlson co-morbidity index was the only predictive factor for late mortality. This information could help to refine the selection criteria for PEG placement.

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