Clinical Nutrition 38 (2019) 856–861

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: http://www.elsevier.com/locate/clnu

Original article

Mortality risk factors after percutaneous gastrostomy: Who is a good candidate?

Ana Agudo Tabuenca [a, *], Jara Altemir Trallero [b], José Antonio Gimeno Orna [a], María Julia Ocón Bretón [a]

[a] Clinical University Hospital Lozano Blesa, Avenida San Juan Bosco, 15, 50009, Zaragoza, Spain
[b] San Jorge Hospital, Avenida Martínez de Velasco, 36, 22004, Huesca, Spain

ARTICLE INFO

Article history:
Received 5 July 2017
Accepted 12 February 2018

Keywords:
Enteral nutrition
Percutaneous gastrostomy
Cognitive impairment
Mortality
Predictive factors
Survival probability model

SUMMARY

Background: The percutaneous gastrostomy tube (PG) is an effective and safe way for the delivery of enteral nutrition. The aim of this study was to identify predictive factors for mortality after PG placement.
Material and methods: An observational and analytical cohort study was conducted. All endoscopic or radiological percutaneous gastrostomy tubes placed between January 2009 and July 2016 were evaluated. Mortality was the dependent variable. Initial clinical and analytical patient features and the development of complications during follow-up were recorded.
Cox regression models were used to evaluate the risk of mortality associated to the studied variables. Hazard ratios with the corresponding 95% confidence intervals were retrieved from these models.
Results: A total of 289 patients underwent PG placement (57% male). The mean age was 70.1 (SD 13.6) years. The median follow-up period was 8.7 (IQR 18) months. One hundred and seventy-four patients died during the follow-up period. The overall mortality rate was 4.8 per 100 patients-month. The highest mortality rate was during the first month after PG placement (13.2 per 100 patients-month), subsequently decreasing.
Multivariate regression analysis showed that age ($HR_{1year} = 1.01$; $p = 0.015$), Charlson comorbidity index ≥ 4 ($HR = 1.69$; $p = 0.011$), the presence of degenerative neurological disease ($HR = 1.69$; $p = 0.012$) or malignancy ($HR = 2.02$; $p = 0.012$) and the development of aspiration pneumonia during the follow-up period ($HR = 3.29$; $p = 0.001$) were statistically significant independent predictive risk factors associated with mortality. A model to predict survival probability prior to placing the PG was developed from the variables of the multivariate analysis.
Conclusion: Mortality after PG placement is high. Older age, higher comorbidity and the development of aspiration pneumonia are predictive factors for mortality. A more careful selection of candidates for PG placement should be done to improve the patient prognosis after the procedure.

1. Introduction

In recent times, percutaneous gastrostomy tube (PG) placement has been used as a safe and effective way of delivering enteral nutrition (EN), both to patients with swallowing disturbances due to neurological disorders, and to those who have a mechanical obstruction to the passage of food [1]. There are three main techniques for gastrostomy tube insertion; the first, the surgical gastrostomy, designed by the Norwegian surgeon Egeber in 1837, is no longer in use [1,2]. The other two are percutaneous techniques, designed in 1980 by Gauderer (endoscopic gastrostomy) and in 1981 by Preshaw (radiologically inserted gastrostomy) [3].

The insertion of a gastrostomy tube should be carried out when the need for EN is estimated to be longer than 4 or 6 weeks, or when it is considered to be permanent. Ideally, the patient should not be suffering from an end-stage chronic disease, and patient life expectancy should be over 2 months [4–8].

Many studies have evaluated the benefits gained by the placement of a PG, without finding any decisive results. This could be due to the heterogeneity of the patients included regarding the cause

* Corresponding author. Calle Monasterio San Martin de Cillas, 17, 3ºA, 50013, Zaragoza, Spain.
E-mail address: a.agudota@gmail.com (A. Agudo Tabuenca).

https://doi.org/10.1016/j.clnu.2018.02.018
0261-5614/

that motivated PG placement, and the differences in their baseline health status [9,10]. Hypoalbuminemia, old age, high anaesthetic risk, dementia, low body mass index, or high Charlson comorbidity index have been postulated as potential predictive factors for mortality after PG placement [11–15].

The aims of this retrospective study were to identify the main predictive risk factors for mortality after PG placement and to establish the survival probability of the patients in accordance with their baseline characteristics. The value of knowing these factors is that they can lead to adequate patient selection and to the rejection of PG placement in patients with a low probability of benefiting from the procedure, due to their short life expectancy.

2. Methods

2.1. Study design

This was an observational and retrospective analytical cohort study, carried out at the University Clinical Hospital Lozano Blesa in Zaragoza, Spain, which provides medical care for around 300,000 people. The study was run by the Nutrition Unit (NU), which comprises four members (two endocrine doctors and two nurses) who are all specialised in clinical nutrition. All patients who underwent a PG placement between January 2009 and July 2016 were evaluated. One of the physicians was responsible for following the patients during hospitalisation, while the other followed up the patients once they were discharged from hospital.

2.2. Inclusion criteria

Regardless of the indication, all patients who underwent a PG placement were included. The placement of the PG was indicated by the physician responsible for the patient along with the NU. The PG was placed either endoscopically, by a team of experienced gastroenterologists, or radiologically, by a team of interventional radiologists. Generally, patients suffering an obstruction or malignancy affecting the tongue, pharynx or larynx underwent a radiological gastrostomy, whereas the remainder underwent an endoscopic gastrostomy. All patients received one gram of amoxicillin-clavulanic acid as a prophylactic antibiotic 1 h prior to the procedure.

Patients who underwent a surgical gastrostomy, those with a jejunostomy tube, those who were not followed up by the NU, and those who were admitted to the intensive care unit at the time of PG placement were excluded from the study.

2.3. Dependent variable

The dependent variable (clinical end-point) was mortality attributed to all causes.

2.4. Independent (predictive) variables

All the variables were collected from the protocol sheet used by the NU in order to follow up patients undergoing a PG placement.

Demographic (age and sex), anthropometric (weight and height, with body mass index (BMI) calculation), clinical (prior diagnosis of diabetes mellitus, presence of oncological or neurological diseases) and biochemical (glucose, creatinine and albumin serum levels and blood count) variables were analysed. The Charlson comorbidity index was used as a way to summarise the health status of the patients included in the study, establishing two categories with the cut-off point at $\geq$4. The Charlson comorbidity index is a method for measuring the impact of comorbid disease, initially designed by Charlson et al., in 1986 (Table 1). The left side of the table shows the score that represents each item. After summing all of them, the final score is obtained. Below 4 means low morbidity, whereas over 4 represents high global morbidity.

Table 1
Charlson comorbidity index.

Assigned weights for diseases	Conditions
1	Myocardial infarct
	Congestive heart failure
	Peripheral vascular disease
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Ulcer disease
	Mild liver disease
	Diabetes
2	Hemiplegia
	Moderate or severe renal disease
	Diabetes with end organ damage
	Any tumour
	Leukaemia
	Lymphoma
3	Moderate or severe liver disease
4	Metastatic solid tumour
	AIDS

The nutritional formula used to nourish the patients was classified as standard or special, adjusted to the patients' needs and disease. Indications for gastric tube feeding were categorised into three main groups: degenerative neurological diseases (dementia or amyotrophic lateral sclerosis (ALS)), malignancies, and other indications (including ictus).

The occurrence of complications after PG placement was monitored during follow-up. They were classified into three main types: digestive (vomiting, diarrhoea or constipation), mechanical (loss or obstruction of the PG during hospitalisation), and infectious (infection of the gastrostomy tube). The development of pressure ulcers and aspiration pneumoniae was also documented.

2.5. Laboratory methods

The determination of biochemical and haematological parameters was carried out by the routine procedures at the hospital laboratory. Glomerular filtration rate, expressed as ml/min/1.73 m^2, was estimated by the CKD-EPI formula.

2.6. Ethical considerations

The collection of the required data was approved by the hospital management, guaranteeing data and patient privacy. Due to the type of study that was undertaken, an approval of the Human Research Ethics Committee was not required.

2.7. Statistical analysis

All the patients who underwent a PG were included in the study. Previous sample size calculation was not undertaken. The mortality rate during follow-up allowed us to detect differences in mortality risk of approximately 20%, with an 80% power and a two-sided α error of 0.05.

Quantitative variables are described by mean and standard deviation (SD), or by median and interquartile range (IQR); and qualitative variables are described by frequency distribution (expressed as a percentage). Comparisons of the characteristics of dead and alive patients were undertaken by using Student's t test and the chi-square test (X^2) for quantitative and qualitative variables, respectively.

Mortality rates were expressed per 100 patients-month. Kaplan–Meier curves were used to compare mortality rates depending on initial patient characteristics, and the differences obtained were evaluated for statistical significance using the log-rank test. The incidence rate of death was used as an indicator of its rhythm of appearance.

Cox regression models were fit to determine the risk of mortality associated to the predictive variables analysed. Hazard ratios (HR) with corresponding 95% confidence intervals (CI) were retrieved from this model. A univariate analysis was initially performed. Subsequently, multivariate analyses were conducted, in which the variables in the models were retained according to their clinical importance and statistical significance ($p < 0.1$ in the univariate analysis). Finally, the best predictive model of mortality was selected by the sequential exclusion procedure. The variables included in the final model were used to determine the patients' probability of survival before PG placement.

Associations with a p value of less than 0.05 were considered statistically significant. Statistical analysis was performed using the SPSS package, version 22.0.

3. Results

A total of 289 patients were included, 164 (57%) of whom were male. Patients' mean age was 70.1 (SD 13.6) years. The median follow-up time was 8.7 (IQR 18) months. An endoscopic gastrostomy tube was placed in 199 (69%) patients, whereas in 90 (31%) the PG was placed radiologically. The individual clinical and anthropometrical characteristics of the patients are listed in Table 2.

Malignancy was the main reason for placing a PG in 101 patients (34.9%), followed by dementia in 69 patients (23.9%), ictus in 44 patients (15.2%), ALS in 34 patients (11.8%), and other causes in 41 patients (14.2%). Regarding malignancy aetiology, 73 patients had head and neck cancer (including tongue, tonsils, uvula, pharynx and larynx), 15 patients had an oesophageal malignancy, four patients had a cerebral tumour, three patients had lung cancer and the remainder had other kinds of malignancies (gastrointestinal, bladder, breast and metastatic melanoma). According to our simplified classification of indications into three groups, the most frequent reason for placing a PG was for degenerative neurological diseases (35.6%), which included dementia and ALS, followed by malignancy (34.9%), and other indications (29.5%).

Table 2
Clinical features of patients based on death or survival.

Variable	Total	Death	Survival	p
Sex male (%)	56.9	57.5	56.1	0.82
Age (years), mean (SD)	70.1 (13.6)	71.8 (13.1)	67.5 (14)	**0.008**
Body mass index (Kg/m2), mean (SD)	23 (4)	22.8 (3.6)	23.2 (4.6)	0.46
Glucose (mmol/l), mean (SD)	6.6 (2.7)	6.55 (2.9)	6.6 (2.55)	0.93
Creatinine (mg/dl), mean (SD)	0.70 (0.33)	0.70 (0.35)	0.69 (0.31)	0.66
Glomerular filtrate <60 ml/min/1.73 m [2] (%)	8.8	10.5	6.2	0.21
Albumin (g/dl), mean (SD)	2.93 (0.64)	2.96 (0.62)	2.89 (0.66)	0.37
Haemoglobin (g/dl), mean (SD)	12 (2)	12 (2.1)	12 (1.9)	0.84
Lymphocytes ($x10^3/mm^3$), mean (SD)	1.453×10^3 (8.03×10^2)	1.389×10^3 (7.58×10^2)	1.547×10^3 (8.60×10^2)	0.449
DM (%)	19.4	20.1	18.3	0.69
Malignancies (%)	34.9	37.9	30.4	**0.002**
Dementia/ALS (%)	35.6	40.2	28.7	
Other/CVA (%)	29.4	21.8	40.9	
Charlson comorbidity index, mean (SD)	2.8 (2.2)	3.1 (2.3)	2.27 (1.9)	**0.001**
Charlson ≥4 (%)	25.3	31.6	15.7	**0.002**
Method (%) Endoscopic	69	67.1	73.5	0.154
Radiological	31	32.9	26.5	
Mechanical complications (%)	5.5	5.8	5.2	0.58
Digestive complications (%)	19.4	21.3	16.5	0.86
PG infections (%)	4.8	5.2	4.3	0.471
PG removal (%)	12.5	6.9	20.9	**<0.001**
Pressure ulcers (%)	4.9	3.4	7	0.17
Aspiration pneumonia (%)	5.9	8.6	1.8	**0.016**
Standard nutritional formula (%)	48.7	50	46.8	0.604

Statistically significant results are written in bold. DM, diabetes mellitus; ALS, amyotrophic lateral sclerosis; CVA, cerebrovascular accident; PG, percutaneous gastrostomy; SD, standard deviation.

Globally, 79 patients experienced a complication due to the procedure. Digestive complications were developed by 19.4% of patients, among which constipation was the most frequent (9.7%), followed by diarrhoea in 4.2% and vomiting in 3.8% of patients. Mechanical complications occurred in 5.5% of patients, which included loss and obstruction of the tube, and despite the prophylactic antibiotics, 4.8% of patients developed PG infections (which included the development of a granuloma, an abscess or any other kind of infection of the gastrostomy tube). Pressure ulcers were detected in 4.9% of patients during follow-up, and 5.9% of patients suffered from aspiration pneumonia. Fifteen of the 17 patients with pneumonia died during the follow-up period.

A total number of 174 patients (60.2%) died during the follow-up period. The causes of death were oncological (67 patients), respiratory failure including aspiration (33 patients), infections (31 patients), heart failure (4 patients) and unknown (39 patients). The global mortality rate was 4.8 per 100 patients-month. Characteristics of studied subjects in accordance with their survival are given in Table 2. The subjects who died during the follow-up period were older, scored higher in the Charlson comorbidity index, and had a higher incidence of aspiration pneumonia and a lower probability of having the PG removed. Median survival was 12.1 months (CI 95% 9.6–14.6 months). The risk of death within 30 days, 12 months, 24 months and 36 months was 13.5%, 50%, 65.3%, and 72%, respectively. The mortality rate was very high during the first month, 13.2 per 100 patients-month. The rate decreased progressively to 6.5 in the second and third months, and to 3.5 from the fourth month onwards, as shown in Fig. 1.

Mortality rates per 100 patients-month were as follows: ALS 7.0, malignancy 5.9, dementia 5.8, ictus 3.1, and others 2.4. Due to the similarity of rates, patients with ALS and dementia, on the one hand, and patients with ictus and other causes, on the other, were put together. Of the patients who died, the majority had the PG placed due to neurological degenerative diseases, followed by malignancies and other causes. Mortality rates were 6.2, 5.9 and 2.7 per 100 patients-month, respectively ($p = 0.002$; Fig. S1). Mortality rates were also higher in patients that scored 4 or higher in the Charlson comorbidity index (7.8 vs 4.1; $p = 0.001$), and in those who suffered from aspiration pneumonia (12.4 vs 4.6; $p = 0.002$). Univariate analysis indicated that factors predicting mortality were older age, Charlson comorbidity index ≥4, insertion of a PG due to neurological degenerative diseases or malignancies, the development of aspiration pneumonia, and the non-removal of the PG (Table 3). The best predictive model of mortality in the multivariate analysis was that composed by age, Charlson comorbidity index, reason for PG placement, and the development of aspiration pneumonia (Table 4). The variables included in the multivariate model set out in Table 4 were used to develop a table which reflects the baseline probability of survival before PG placement (Table 5).

Due to the length of the evaluated period, sensitivity analysis was performed, splitting the follow-up time into two periods: the first between January 2009 and December 2011, and the

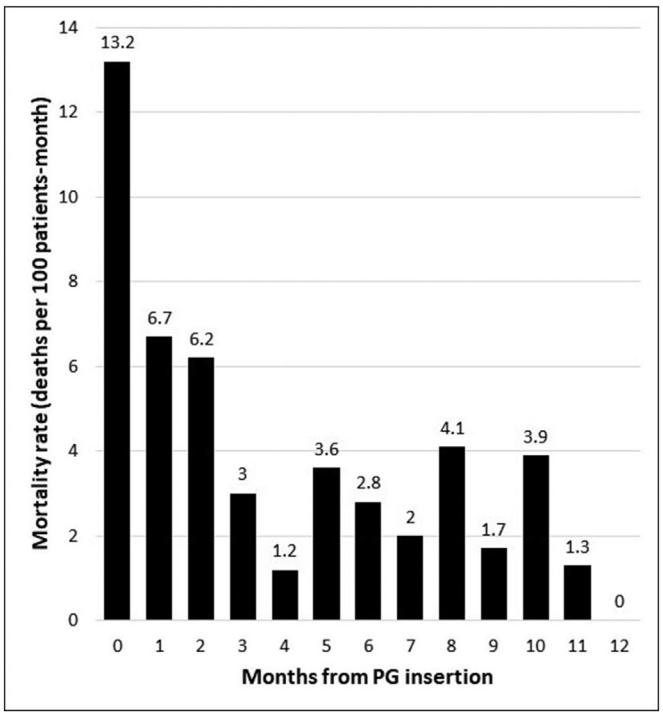

Fig. 1. Global mortality rates in deaths per hundred patients/month are shown here. Note that the highest mortality rate occurred during the first month after placing the PG.

Table 3
Mortality predictive factors in univariate analysis.

Variable	HR	95% Confidence interval	p
Age	1.018	1.006–1.029	0.002
Malignancies	1.886	1.263–2.815	0.002
Neurological degenerative disease	1.926	1.294–2.866	0.001
Charlson ≥4	1.744	1.266–2.404	0.001
Aspiration pneumonia	2.246	1.319–3.825	0.003
PG removal	0.376	0.209–0.677	0.001

HR, hazard ratio; PG, percutaneous gastrostomy.

Table 4
Mortality predictive factors in the multivariate analysis. A higher X^2 score indicates higher predictive capacity.

Risk factor	HR	95% Confidence interval	p	X^2
Age	1.019	1.003–1.035	0.015	5.95
Charlson ≥4	1.687	1.136–2.505	0.011	6.48
Aspiration pneumonia	3.289	1.775–6.092	0.001	10.87
Malignancies	2.016	1.217–3.340	0.012	8.83
Neurological degenerative diseases	1.693	1.037–2.763		

HR, hazard ratio.

second between January 2012 and July 2016. No statistically significant differences were found; the mortality rate in the first period was 6.4, and in the second period it was 4.2 per 100 patients-month.

4. Discussion

The major finding of this study was a very high mortality rate after PG placement, especially within the first month (over 13%). The main factors predicting mortality risk were older age, high scores in the Charlson comorbidity index, neurological degenerative diseases or malignancies as cause for PG placement, and development of aspiration pneumonia during the follow-up period.

Our findings are in keeping with previous studies in which hypoalbuminemia, age, comorbidity and dementia were reported as risk factors that increase mortality after PG placement for nutritional support [16–19]. There is, however, an enormous dispersion of the analysed variables.

In our study, baseline serum albumin level has not been statistically associated with worse progress. This could be explained by the fact that, in a wide range of subjects, the condition for which the gastrostomy tube was placed was cognitive impairment, which is usually a chronic condition, in which albumin levels are not affected. Nevertheless, albumin is not a good nutritional marker, given that it is quickly affected by acute stress or infections. We found the Charlson comorbidity index to be a relevant risk factor associated with mortality, but few other studies have also proved this [12,20]. The impact of older age on mortality after PG placement has also been reported; Yurdagül Zopf et al. analysed mortality risk in 787 patients after PG placement, and concluded by showing that the mortality rate increased by around 3% with every year of age [21].

The most frequent reasons in our study for PG use were neurological diseases, including dementia, ALS and ictus (50.9%), followed by malignancies (34.9%). Neurological diseases were also the main reason for nutritional support via PG in previous studies [22]. The prevalence of malnutrition in patients who suffer from dementia reaches 70%. The reasons for this are multifactorial. The need for a PG in patients diagnosed with ALS comes from the associated malnutrition and dysphagia. To our knowledge, there are no clinical trials in which increased survival rates after PG placement in these groups of patients has been proved. Nevertheless, a reduction of mortality has been verified in prospective observational cohort studies in these patients [23].

Given that percutaneous gastrostomy tubes are usually placed in seriously ill people, it is usually complicated to show the benefits they can provide. Global 30-Day mortality after the procedure varies between 5.8% and 26% in different studies [24,25]. In most of them, the underlying patient comorbidity accounts for this mortality rate. In our study, over 13% of subjects died within the first month of follow-up, and 60.2% during the entire follow-up period. The median length of survival was 12 months. These results are similar to those reported in comparable studies [13] such as the one by Kurien et al., who analysed one of the largest patient series and found mortality rates of 11.2% at 30 days and 41.1% at one year after PG placement [26]. For these reasons we propose a more careful selection of candidates for PG placement, trying to exclude those with limited life expectancy, who would probably get no benefit from PG placement. Subjects affected by neurological degenerative diseases or malignancies had higher mortality than those affected by other illnesses. The safety and effectiveness of the PG in patients affected by dementia compared to those affected by other diseases is still controversial. Abu et al. showed in their study how patients with cognitive impairment that had a PG inserted had neither a higher survival rate nor a lower risk of re-hospitalisation, compared to subjects affected by other diseases. They established dementia as an independent predictor of mortality [27].

One important finding of our study was that the main risk factor associated with mortality (HR = 3.3) was aspiration pneumonia, which is in agreement with the work of Light, in which aspiration, urinary tract infection and age older than 75 years were the independent risk factors for mortality [25]. It is well established that gastro-oesophageal reflux and aspiration pneumonia can lead to the death of a patient. Factors associated with the onset of aspiration pneumonia are diminished consciousness and the supine

Table 5
Survival probability predictive model.

Months from PG					1	3	6	12	24
	Age	Charlson	Aetiology	Pneumonia					
Survival probability depending on the characteristics of the subjects	Age ≤72 years	Charlson <4	Other	No	0.9424	0.8806	0.8392	0.7369	0.6188
				Yes	0.8773	0.7553	0.6791	0.5097	0.3467
			Malignancy	No	0.8929	0.7845	0.7155	0.5583	0.3999
				Yes	0.7788	0.5852	0.4777	0.2762	0.1323
			Neurological degenerative	No	0.9091	0.8153	0.7546	0.6125	0.4627
				Yes	0.8104	0.6372	0.5372	0.3389	0.1825
		Charlson ≥4	Other	No	0.9165	0.8295	0.7728	0.6383	0.4937
				Yes	0.8249	0.6619	0.5661	0.3712	0.2106
			Malignancy	No	0.8466	0.6998	0.6113	0.4244	0.2599
				Yes	0.6924	0.4548	0.3374	0.1508	0.0511
			Neurological degenerative	No	0.8693	0.7407	0.661	0.4863	0.3219
				Yes	0.7341	0.5155	0.401	0.2037	0.082
	Age >72 years	Charlson <4	Other	No	0.9048	0.807	0.744	0.5975	0.445
				Yes	0.8018	0.6229	0.5207	0.3209	0.1675
			Malignancy	No	0.8261	0.664	0.5686	0.3741	0.2132
				Yes	0.656	0.4051	0.2876	0.1142	0.033
			Neurological degenerative	No	0.8516	0.7087	0.622	0.4374	0.2725
				Yes	0.7014	0.4676	0.3506	0.1612	0.0567
		Charlson ≥4	Other	No	0.8632	0.7295	0.6474	0.469	0.3041
				Yes	0.7227	0.4986	0.383	0.188	0.0723
			Malignancy	No	0.7551	0.5477	0.436	0.2356	0.103
				Yes	0.5379	0.2648	0.16	0.0411	0.0066
			Neurological degenerative	No	0.7896	0.6027	0.4975	0.2964	0.1478
				Yes	0.5936	0.327	0.2141	0.0683	0.0147

position [28]. Despite some authors believing that it can be prevented by placing the gastrostomy tube in a post-pyloric rather than a gastric location, there is insufficient evidence to support this.

One of the strengths of the present study is its external validity. We performed an exhaustive follow-up over almost eight years of the evolution of all percutaneous gastrostomy patients, who were controlled by the NU of the hospital. This has allowed us to describe mortality after PG placement and to identify the risk factors that may reduce patient survival. The survival probabilities depicted in Table 5 can be used by the clinician as a guideline to adopt the best decisions regarding the convenience of placing a PG.

Nevertheless, there are also some limitations that could compromise the study's internal validity. Firstly, because of its retrospective design, a formal sample size calculation was not undertaken and therefore the study could be underpowered to detect the statistical significance of some of the studied variables. Furthermore, some patient data could have been missing. However, due to the thorough records in the NU of all the analysed variables, no significant loss of information was expected. Secondly, the values of some variables that could have been relevant for patient survival, such as inflammatory markers, were not available. Thirdly, the causes of death and the reasons for PG placement had to be collected in broad categories because of the limited number of subjects. Finally, the study was conducted over a very long period, which may have led to some modifications in the selection criteria of the subjects for PG placement over time. Nevertheless, although survival was numerically longer in the second period, the difference was not statistically significant; hence a period effect was not found.

In conclusion, we can affirm that mortality after percutaneous gastrostomy is high. This study suggests that older age, higher patient comorbidity, baseline degenerative neurological or oncological diseases and the development of aspiration pneumonia are associated with early mortality after percutaneous gastrostomy tube placement. We have been able to build a model to predict the survival probability of the individual patient before the procedure. In order to decrease mortality rates after percutaneous gastrostomy, we suggest making a careful selection of candidates, excluding those with a short life expectancy, as well as exhaustively preventing the risk of aspiration during follow-up.

Conflict of interest

None declared.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.clnu.2018.02.018.

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