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Percutaneous endoscopic gastrostomy: Patients' outcomes, adequacy and quality of information given to decision-makers and procedure acceptance

Petros Stathopoulos, George Karamanolis, Ioannis S. Papanikolaou, Dimitrios Polymeros, Angelos A. Papadopoulos, Konstantinos Triantafyllou

Attikon University General Hospital, Athens, Greece

Abstract

Aim We aimed to evaluate patients' survival and complications after percutaneous endoscopic gastrostomy (PEG) tube placement, the quality of information given to the decision-makers (relatives) before the procedure and their overall acceptance of the intervention.

Methods We interviewed the relatives of 35 patients who underwent PEG tube placement in our facility from January 2008 to December 2009, using a structured questionnaire.

Results Thirty-day survival rate was 83%. The cumulative median survival was 35 (95% CI: 27.7-42.3) days and it was not related to patient's underlying condition. No patient died due to procedure related complication. Apart from topical skin reactions (26%), major complications, such as pneumonia, diarrhea, vomiting and tube misplacement were not common (3-11%). Although 83% of the decision-makers considered that they had provided an informed decision after being given comprehensive information about the procedure, 71% said that they had not adequately been informed about alternative methods. One third of the relatives considered that the intervention met their expectations and 67% of them would recommend PEG to other patients suffering from dysphagia. However, only 26% of decision-makers would consent again for PEG tube placement for their patient, while 69% did not answer this question.

Conclusion Patients' outcomes after PEG tube placement are favorable. However, several decision-makers are not satisfied with the quality of information given before informed consent while the acceptance of the intervention is not very high.

Keywords percutaneous endoscopic gastrostomy, outcome, acceptance, information, decision-makers

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Introduction

Percutaneous endoscopic gastrostomy (PEG) tube placement is widely used to provide feeding for patients suffering from dysphagia, due to various causes of oral intake inability or those who need supplemental feeding. However, not all patients benefit from the intervention and efforts are focused on improving patients' quality of life, rather than just prolonging it [1,2]. Therefore, patients' selection is of paramount importance in order not to provide PEG in futile cases. It has been proposed to avoid PEG in demented patients, since it does not provide a meaningful life prolongation[2] and to offer a 30-60 days "cooling" period with nasogastric tube feeding before PEG tube insertion in hospitalized patients, in order to prevent early death and to achieve long-term nutrition [3]. Moreover although PEG is relative safe, it can be associated with significant early and late complications, which can be minimized with thorough knowledge of the procedure's indications and contraindications, its steps and the early recognition of complications [4].

Beyond the above clinical and ethical dilemmas, literature has revealed flaws regarding informed consent procedure before PEG. These include not respecting the feelings and attitudes of family members towards gastrostomy feeding

Hepatogastroenterology Unit, 2nd Department of Internal Medicine - Propaedeutic, Attikon University General Hospital, Medical School, Athens University, Athens, Greece

Conflict of interest: None

Correspondence to: Konstantinos Triantafyllou, Hepatogastroenterology Unit, 2nd Department of Internal Medicine - Propaedeutic, Attikon University General Hospital, Medical School, Athens University, Athens, Greece, Rimini 1, Chaidari, Greece. Tel. +302105832090; Fax. +302105326422; e-mail. ktriant@med.uoa.gr

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and providing insufficient information on alternative feeding options and on the complications of PEG [5-8]. Moreover, to date, evaluation of long-term nutritional support given by PEG from the perspectives of the relatives who take care of the patient has received little attention.

We aimed to evaluate patients' survival and complications rate after PEG, the quality of the information given to decision-makers (relatives) and to determine the overall acceptance of the procedure by them.

Patients and methods

In our facility the decision for PEG tube placement is made by the treating physician, the endoscopist and the patient or his/her care giver after thorough examination of the patient and his record and after receiving informed consent from the patient and the family decision-maker (if the patient is incompetent). Candidate patients do not formally undergo a "cooling" period before tube insertion. However, we stress our efforts to secure that we do not offer the procedure to futile cases. Informed consent is always written and it is received either by the treating physician or the endoscopist, after comprehensive discussion, a couple of days before the procedure. We use the pull technique while the patient is on conscious sedation, monitored usually by an anesthetist. We always give antibiotics before the procedure. Within the first 24 hours after the procedure, the patient is fed and he/she is discharged 48 hours later, with written instructions on feeding, stoma care and early recognition of tube dysfunction.

For the purpose of the study, we interviewed by telephone the decision-makers, who at the same time were the care-givers of patients who underwent PEG tube placement between January 2008 and December 2009 in our facility. We asked about patient's status (dead or alive) and about the complications that might have occurred after the intervention. Moreover, using a structured questionnaire specifically designed for the purpose of our study we assessed: i) the quality of information given to decision-makers before consent for the procedure (four questions), ii) the impact of PEG on patient's (three questions) and family's (three questions) quality of life and iii) the acceptance of the procedure (three questions).

Statistical analysis

Data are presented as absolute value and value percent for categorical variables and as mean value ± standard deviation for scale variables, respectively. Univariate analysis for categorical variables was performed using chi square and Fisher's exact tests, as appropriate. Regarding survival, data are presented as median value (95%CIs) and time-life analysis was performed using Kaplan-Meier curves and the Log rank test. A p value of <0.05 indicated statistical significance.

Results

Between January 2008 and December 2009, 52 patients underwent PEG tube placement for eating disorders or dysphagia in our facility. We could not contact any family member of seven of them, and we did not find the decision-maker of six more patients. Moreover, four decision-makers denied participating in our study. Therefore, we included 35 patients, 25 males, aged 71.5±13 years. The indication for PEG is presented in table 1.

At the time of evaluation 15 (43%) patients were alive (3 of them still on PEG). The cumulative median survival was 35 (95% CI: 27.7-42.3) days [Fig. 1] and it was not related to patient's sex (Log Rank chi square test= 0.02, p=0.9), age (≤75 years vs. >75 years, Log Rank chi square test = 0.11, p=0.74) and PEG's indication (as in table 1, Log Rank chi square test = 5.41, p=0.25)

Thirty-day mortality rate of the procedure was 17% and it was not related to patient's sex (p=0.65), age (p=0.4) and indication for PEG (p=1).

Relatives reported that no patient died due to procedure related complications. Table 2 shows that apart from topical skin reactions-inflammation (26%), major complications, such as pneumonia, diarrhea, vomiting and tube misplacement

Table 1 Indications for percutaneous endoscopic gastrostomy tube placement

Indication, N=35	n (%)
Head, neck and oesophageal cancer	7 (20)
Stroke	12 (34.3)
Dementia	6 (17.1)
Parkinson's disease	4 (11.4)
Amyatrophic lateral sclerosis	1 (2.9)
Other	5 (14.3)

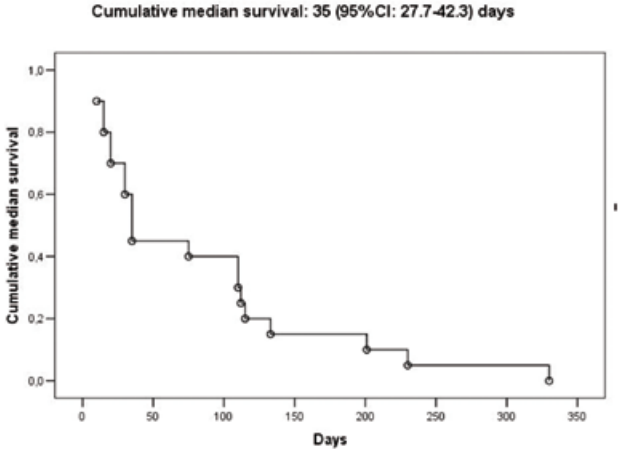

Figure 1 Kaplan-Meier plot of survival of our patients

Table 2 Percutaneous endoscopic gastrostomy tube placement complications reported by the relatives

Complications	n(%)
Death	0
Pneumonia	3 (8.6)
Stoma infection	2 (5.7)
Tube displacement	3 (8.6)
Tube (or stoma) leak	5 (14.3)
Diarrhea	4 (11.4)
Vomiting	1 (2.8)
Skin irritation	9 (25.7)
Sleep disturbance	3 (8.6)
Dressing difficulty	1 (2.8)
Ambulatory difficulty	2 (5.7)

were not common (3-11%).

Regarding the informed consent procedure, 83% of the decision-makers considered that they provided an informed decision after being given comprehensive information about the procedure. However, 71% said that they had not adequately been informed about alternative methods and only 48.6% of them were adequately informed about procedure's complications, including death. Twenty-five (71%) relatives rated the overall adequacy-quality of the information that they received before PEG as good [Table 3].

Table 4 summarizes relatives' perceptions on the improvement of patient's and family's quality of life after PEG tube insertion. Less than half of them believed that PEG

Table 3 Decision-makers (N=35) rate the adequacy-quality of information that they received before consenting for percutaneous endoscopic gastrostomy (PEG)

	Yes, n (%)	No, n (%)	Don't know/don't answer, n (%)
Did you have the opportunity to decide after being given adequate information for PEG tube placement?	29 (82.9)	0	6 (17.1)
Had you been adequately informed regarding PEG complications, including death?	17 (48.6)	8 (22.8)	10 (28.6)
Had you been adequately informed regarding modalities of feeding other than PEG?	3 (8.6)	25 (71.4)	7 (20%)
	Good	Average	Don't know/don't answer, n (%)
Overall, how do you judge the adequacy of your information regarding the procedure and its complications?	25 (71.4)	5 (14.3)	5 (14.3)

Table 4 Decision-makers' (N=35) perceptions on the effect of percutaneous endoscopic gastrostomy (PEG) tube placement on patient's and family's quality of life

Did PEG tube placement improved …	Yes, n (%)	No, n (%)	Don't know/don't answer, n (%)
… patient's quality of life?	17 (48.6)	12 (34.3)	6 (17.1)
… patient's underlying condition?	5 (14.3)	18 (51.4)	12 (34.3)
… patient's nutrition status?	26 (74.3)	4 (11.4)	5 (14.3)
Did PEG tube placement improved family's quality of life regarding …			
… patient's care overall?	17 (48.6)	3 (8.6)	15 (42.9)
… the time required for patient's care?	10 (28.6)	6 (17.1)	19 (54.3)
… the overall costs of patient's care	0	4 (11.4)	31 (88.6)

improved patient's and family's quality of life and one third of them considered that the intervention met their expectations.

Finally, 68.6% of decision-makers would recommend PEG to other patients suffering from dysphagia. However, only 26% of them would consent again for PEG tube placement for their patient, while 69% of them did not answer this question [Table 5].

Discussion

Our study is the first that combines the evaluation of patients' outcomes after PEG tube placement, and the perception of the decision-makers on the quality of the informed consent procedure, on the quality of life of PEG patients and their families and on the overall acceptance of the procedure. We report low early mortality and complications rates but also questionable informed consent procedure and acceptance of the intervention.

Percutaneous endoscopic gastrostomy is a safe procedure, associated with low complication risks and low procedure-related mortality. However in the most recent studies, the 30-day mortality (early mortality) ranges from 6.5%-30% [5,9-11]. Our 30-day mortality was 17% which was a little higher than that reported from our group eight years ago [5]. Interestingly the cumulative median survival was identical in our two studies. The largest audit published to date [6] that examined the factors associated with the early death of 719 patients after PEG showed that the median time to death was only 9 days after PEG insertion. The consultants who were responsible for the procedure answered a postal questionnaire to evaluate the causes of 30-day mortality and to grade the anticipated risk of death retrospectively. They responded that early death was due to respiratory (71%), central nervous system (50%), cardiovascular (24) and renal (5%) disorders, while 1.5% died from hepatic failure (multiple answers were permitted). Moreover, they stated that 482 patients had a definite or greater risk of dying within 30 days.

Table 5 Decision-makers' (N=35) overall acceptance of percutaneous endoscopic gastrostomy (PEG) tube placement

	Yes, n (%)	No, n (%)	Don't know/ don't answer, n (%)
Have your expectations been met regarding PEG tube placement in your patient?	11(31.4)	15 (42.8)	9 (25.8)
Not that much		11(31.4)	
Not at all		4 (11.4)	
Would you consent for PEG tube placement in your relative again, if needed?	9 (25.7)	2 (5.7)	24 (68.6)
Would you recommend PEG tube placement in other patients with similar disorders?	24 (68.6)	3 (8.6)	8 (22.9)

This high early mortality rate might reflect a higher risk population undergoing the intervention, such as elderly with cerebrovascular accidents [12] or patients who are unlikely to benefit from PEG, such as demented patients [2,13]. Seventeen (48.6%) patients in our study were aged >75 years, 12 (34.3%) were referred for PEG after stroke and 6 (17.1) were demented.

While others report many factors, mainly age [5,6,10,14], underlying condition (cancer, heart disease, dialysis) [6,10,15], non white race [10], being married [10], female gender [14] and aspiration pneumonia [15] associated with early death after PEG, the study from Brazil [9] revealed that C-reactive protein was the only factor predicting early mortality and that low performance status predicted late mortality. We did not find any association of either the 30-day or the overall mortality with patient's sex, age and underlying condition. Our results are in agreement to those reported by us previously with the exception of cumulative mortality which in the 2002 study was higher in patients aged > 75 years. A possible explanation of this discrepancy and the discordance with the reports from the other mentioned groups might be the small number of patients included in our studies, which may lead to a type-II statistical error.

In our study, patients' relatives reported low post-procedure complication rates. No death was reported and major complications such as aspiration pneumonia were scarce. Only stoma area irritation was reported at a rate higher than 20%, while other minor complications were infrequent. There is a possibility that the complication rates might be either under or overestimated by the decision-makers and these rates may not reflect reality. However, it was the purpose of the study to calculate the decision-makers reported complication rates and therefore, it is difficult to compare our results with the complication rates reported by health care providers or derived from patients' records [16].

A comprehensive clinical review describes the most commonly encountered PEG complications, as well as strategies to avoid them [4]. Authors divide these complications to 1) PEG procedure-related complications, such as, pneumoperitoneum, portal and mesenteric venous gas, colon, small bowel, liver and splenic injuries, intra-, retroperitoneal and abdominal wall bleeding, and 2) Complications associated with PEG use and stoma care, namely wound infection and abscess, necrotizing fasciitis, buried bumper syndrome, peristomal leakage, PEG site herniation, gastrointestinal ulceration and bleeding, gastric outlet obstruction, ileus, gastroparesis, bowel and gastric volvulus associated with PEG, tube dislodgement and clogging, diarrhea, aspiration and tumor implantation at PEG site.

In our study, more than 80% of the decision-makers

considered that they were adequately informed prior to PEG tube placement but less than half of them felt that they were adequately informed about the complications of the procedure. Furthermore, 71% of the relatives complained about inadequate information given to them regarding alternative feeding methods. This last figure is almost thrice the one (25%) reported in the 2002 study [5], while the rest of our results regarding informed consent procedure have not improved since 2002.

Similar to our reports, published studies point out that the information given before PEG placement is often inadequate. In the study of Callahan et al [17], nearly half of patients undergoing gastrostomy placement (or their relatives) reported that no alternatives had been discussed before the procedure, while in another study the potential complications of PEG were not discussed with the decision-makers in 46% of the cases [18]. Most recently, a survey from the United Kingdom showed that patients and care-givers might not be given even the choice to decide for PEG while only 40% of the patients reported that they received sufficient information regarding the intervention [7]. Moreover in a population of geriatric patients in Israel, only 40% of the family members received complete information about PEG, 35% received information about alternative feeding methods and only a quarter of them were fully informed about the procedure's complications. More importantly, almost 60% of the family members felt that they were pressured to consent for PEG. Overall, approximately 50% of them were dissatisfied with the decision-making process [8], while this figure in our study was slightly below 30%.

Earlier studies also revealed that fully informed patients or their surrogates might in fact decline tube feeding. For example, O'Brien et al [19] report that of 379 mentally competent nursing home residents only 33% expressed a preference for tube feeding in case they would become unable to eat and in an interview study [20] only 28% of 121 competent patients with amyotrophic lateral sclerosis favored feeding by gastrostomy.

Informed consent is a complex procedure, while physicians must give full and unbiased information to patients/relatives, provide adequate time for discussion and encourage them to actively participate in the decision-making process [21,22]. Beyond the general difficulties of what, how much and who (the endoscopist or the treating physician) will give the patient/decision-maker information, informed consent process is even more delicate in PEG cases, since the patient, might be incompetent and someone else must decide for his/her own well-being. Therefore the procedure might be even more stressful for the doctor and for the patient's relative, especially if there is not enough time left to decide and if the information focuses only on the benefits of feeding underestimating the risks and the overall prognosis of the patient [23]. This is another reason to recommend a "cooling" period before tube insertion [3]. During this period, early PEG mortality may diminish and patient's relatives have the opportunity to recognize his/her patient's poor prognosis and therefore to decide against PEG.

Beyond just prolonging life, quality of living is more important. Counting quality of life is always difficult. Most researchers measure health related quality of life by using specific questionnaires pertaining to its most important components that include physical, psychological and social domains of health. Although the objective dimensions are important to defining a patient's degree of health, for the purpose of the study we decided to ask specific questions on patient's caregivers subjective perceptions and expectations that translate the assessment into the actual quality of life experienced by them or expected for their patient. Overall, less than half of the responders considered that PEG tube placement improved patient's and family's quality of life and this is in agreement with the results of the 2002 study. The majority of relatives anticipated that the intervention improved patient's nutrition and they also understood that PEG did not improve patient's underling illness. Moreover, many of them were skeptical regarding the resources required, in terms of time and money, by the family for the care of the patient after PEG tube insertion. This is in contrast with the results of the 2002 study when relatives said that after PEG, it was easier to manage the patient (96%), the time for patient care was diminished (62%) and the cost of care was reduced (11%). However, there is no explanation for this discrepancy.

In a United Kingdom study, 24 of the 27 care-givers of demented patients felt that PEG feeding was successful [7] and in a study from Pakistan ease in feeding was noted by 84% of the care-givers/patients, while dependency on others for feeding was noted by 36% of the respondents [16]. Similar to our results, a significant proportion of care-givers/patients (49%) had the impression that feeding through PEG-tube increased the overall costs of care in such patients [16].

Apart from clinical outcomes and health related quality of life improvement, patients' and decision-makers' acceptance of the procedure is of paramount importance. Less than one third of our responders felt that their expectations had been fulfilled regarding PEG tube feeding. Interestingly, while 24 of the 35 decision makers would recommend PEG feeding to other patients, only 9 of 35 would again consent toPEG tube placement to their patient. This strange discrepancy might in part be explained by the uncertainty relatives experience on whether they have properly decided for their patient. This might also explain why only 26% of the decision makers in the Israeli survey felt that their patient him/herself would have consented to PEG and why only 24% of them would consent having PEG themselves [8]. Furthermore, Verhoef and Van Rosendaal [25] reported earlier that 41% of caregivers would have decided not to have PEG feeding themselves if they were in the same situation as the patient.

In contrast to the above reports, the Pakistani study showed that the majority (60%) of patient/care givers would like to have PEG tube again, if required [16], 70% of the decision-makers in the United Kingdom survey would have PEG reinserted if given the choice again [7]and most (87%) of the decision-makers in our 2002 study believed that their decision was correct and they would recommend PEG (84%) to other patients suffering from dysphagia [5].

The major strength of our study is that we present the opinions, feelings and perceptions of people who have taken a

decision for an intervention on behalf of an incompetent relative and who thereafter take care of him, in real life. However, the study has several limitations, such as, retrospective design, limited number of patients included, heterogeneous population and use of non validated questionnaires. Moreover, we had many "Don't know/don't answer" answers reflecting the uncertainty of the responders. Whether this observation is a limitation or strength of a "real life" survey cannot be easily answered.

In conclusion, our results show that patients' outcomes after percutaneous endoscopic gastrostomy tube placement are favorable. However, several deficiencies in the decision-making process have been identified and must be addressed properly. These violate patients' and/or decision-makers' self-determination, they negatively influence the doctor-patient partnership and might lead to malpractice claims. Although some decision-makers believe that PEG feeding improved patient's and family's quality of life, they are skeptical to re consent for PEG, limiting the acceptance of the intervention at the same time.

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