Percutaneous Endoscopic Gastrostomy (PEG) feeding in the enteral nutrition of dysphagic stroke patients

A West Midlands Development and Evaluation Service Report

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QUESTION ADDRESSED BY THIS REVIEW:

Is percutaneous endoscopy feeding more effective than nasogastric tube feeding in stroke patients requiring enteral feeding with regard to mortality, morbidity and health related quality of life?

CONCLUSION:

PEG feeding of dysphagic stroke patients is associated with small increases in patient wellbeing and small differences in resource use compared with NGT feeding. The impact of enteral feeding of stroke patients on survival without severe disability is unknown. Trials in progress may provide further information.

EXPIRY DATE: 2002

This report was completed December 1999. The searches were conducted in September 1998. The expiry date of this report is provisionally December 2002, but is dependent upon the reporting of the Pegasus and FOOD trials which should provide new evidence on this topic.

West Midlands Development & Evaluation Service

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Contribution of Authors

Carole Cummins undertook the collection and collation of evidence and wrote this review. Amanda Burls provided duplicate data extraction and commented on the report. Tom Marshall provided extra material on health economics.

West Midlands Development and Evaluation Committee Recommendation:

Supported

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Contents

Summary

Technology

Percutaneous endoscopic gastostomy (PEG) is a method of enteral feeding through a gastrostomy tube placed endoscopically under local anaesthesia and sedation. It is an alternative to nasogastric tube (NGT) feeding.

Condition

The main use of PEG is for the enteral feeding of dysphagic stroke patients.

Evidence of effectiveness

Three small RCTs have compared PEG and NGT feeding. The evidence indicates that PEG feeding is technically superior to NGT feeding and is more acceptable to patients. One trial found that early PEG feeding was associated with a reduction in mortality, but this result needs to be confirmed.

Economic analysis

Compared to NGT feeding, PEG feeding is associated health gains including improved patient wellbeing and possibly earlier discharge. There are small differences in the resource implications of PEG compared to NGT, principally that PEG requires the use of more senior staff.

Conclusion

PEG feeding of dysphagic stroke patients is associated with small increases in patient wellbeing and small differences in resource use compared with NGT feeding. The impact of enteral feeding of stroke patients on survival without severe disability is unknown. Trials in progress may provide further information.

1 Introduction

Percutaneous endoscopic gastostomy (PEG) is a method of enteral feeding through a gastrostomy tube placed endoscopically. The procedure can be performed with benzodiazapine sedation and local anaesthetic in patients who are high anaesthetic risks. The method has low morbidity and a procedure related mortality of 1 to 2%.[1 2]. Percutaneous gastrostomy tubes can also be inserted as a radiological procedure[3 4]

This method of enteral feeding is increasingly used in long term feeding of dysphagic patients (patients with swallowing difficulties), the majority of whom have had strokes, with a minority suffering from other neurological indications, principally motor neurone disease, or with a need for nutritional support for other reasons including malignancy[5 6 7].

The selection of patients for PEG and the timing of PEG insertion are important. Some patients are likely to die quickly as a result of their strokes whether or not enteral feeding is initiated and will therefore derive little benefit from this invasive procedure. Other patients may survive with maximal dependency and minimal quality of life[1]. The impact of enteral feeding on survival and quality of life is currently unknown.

Ethical guidelines for PEG placement[8] have suggested that PEG is not ethically justified where the patient will derive no physiological benefit (as in permanent cachexic states) and where the patient will not experience any improvement of quality of life (as in permanent vegetative states), with PEG only enabling the maintenance of physiological function. Where dysphagia exists without complications, and the patient will unequivocally benefit, then PEG feeding is ethically justified. Where PEG is of uncertain clinical benefit, because of deficits in quality of life or progressive underlying disease, the authors state that the decision to have a PEG should be made by patients or substitute carers after receiving full information from the clinician. Most stroke patients considered for PEG will fall into the latter category.

2 Background

2.1 Incidence of dysphagia in stroke patients

Dysphagia, that is difficulty in swallowing, is a common, serious consequence of stroke and results from damage to the upper motor neurone of the lower cranial nerves. In an unselected hospitalized group of stroke patients, 45% had difficulty in swallowing when admitted to hospital, 7% had dysphagia for nine or more days, but only 3% were dysphagic after 40 days, with a 6 week mortality rate of initially dysphagic patients of 46%[9]. In a series of hemispheric stroke patients, although nearly 30% of stroke patients who were conscious within 48 hours of their stroke initially had difficulty swallowing, by 1 month, only 2 percent still had dysphagia[10].

It has been estimated, using data from the above studies, that a typical district general hospital serving a population of 280,000 will have approximately 8-10 patients out of 450 new stroke

patients per year with dysphagia persisting 14 days[1]. Approximately 30 patients, however, will have dysphagia persisting more than a week and will be candidates for early nutritional support.

2.2 Natural history, health related quality of life and functional status

The health related quality of life of dysphagic stroke survivors will vary with functional status following stroke. Dysphagia is associated with severe stroke. Although most dysphagic patients either recover their swallowing ability or die[9 10] in the first few weeks following the stroke, some patients regain the ability to eat at a later stage. Little information is available about the functional status of dysphagic stroke patients in the longer term.

Although dysphagia has a poor prognosis and is associated with early death following stroke[9], medium term survivors with dysphagia are probably not at greater risk of death than patients with otherwise comparable functional status without dysphagia. Dysphagia, however, is associated with poorer functional outcome[10].

Patients with dysphagia are at a high risk of aspirating their food and consequently of aspiration pneumonia. Enteral feeding does not remove this risk[11] but does contribute to an improved nutritional status. Malnutrition has been associated with poor outcomes, including higher rates of urinary and respiratory infections and a higher prevalence of bedsores, but it is not clear whether early enteral nutrition of any type prevents increasing malnutrition following stroke[12]. A small observational study has found that pneumonia prior to PEG, oesophagitis on endoscopy and age of 70 or over were risk factors for pneumonia after PEG[13].

Even in community series, the reported proportion of stroke patients achieving independence (variable definitions) at one year varies from 60 to 69%, with best estimates of 45% achieving independence at 6 months and 60% by one year. Around 20% of survivors are in institutions one year after the stoke[14]. One community based study found that at 6 months 4% were very severely disabled, 5% were severely disabled, 12% were moderately disabled, 32% were mildly disabled and 47% were independent in activities of daily life on the Barthel Index of Daily Living. By definition, survivors with dysphagia are at least mildly disabled (Barthel Index 15-18). That is, no patients are able to perform all self-care activities.

Raha and Woodhouse[6] comment “the target population is, by definition, markedly disabled, usually with severe underlying disease”. They believed that, in these circumstances, PEG improved their patients’ quality of life in their final weeks. The reasons put forward for this were that PEG feeding allows relief from hunger to be provided where the patient was able to communicate that they were hungry and patients preferred PEG over NGT on grounds of comfort and cosmetic acceptability[6 15].

2.3 Numbers of patients treated

Dysphagia following stroke is likely to be the indication for at least half of all PEG insertions in a district general hospital[15]. Hospital Episode Statistics for the West Midlands from April 1996 to March 1997 recorded 411 gastrostomies, of which 57% were specified as endoscopic (Table 1). Most gastrostomies where the approach was unspecified would have been PEGs, rather than open operations. Stroke patients accounted for 270 gastrostomies, 66% of the total. Some of the ninety patients described only as dysphagic would also have suffered strokes.

Calculations based on the incidence of persistent dysphagia given above (see 3.1) suggest that, in 1995, the West Midlands (population 5,315,000) would have had around 600 stroke patients with dysphagia persisting for at least a week and between 150 and 190 new stroke patients with dysphagia persisting for 14 days[16]. The number of gastrostomy procedures carried out in stoke patients suggests that nutritional support has often been provided at an early stage. This is supported by audit figures from West Midlands hospitals *(personal communication)*.

A high proportion of these patients were seriously ill, as 29% of the total and 35% of the stroke patients died during the admission in which the gastrostomy was carried out.

Gastrostomies were usually carried out as part of an inpatient stay, although there were a few day cases (19 (5%) of the total, 7 (3%) of stroke patients). Inpatient length of stay by diagnosis is given in Table 2. Some gastrostomies were carried out during the course of very long admissions, and the median length of admission for stroke inpatients who had a gastrostomy was 46 days.

Table 1: Gastrostomies, type and diagnosis, West Midlands Hospital Episode Statistics 1996-1997

	Gastrostomy type						Total	
	permanent	temporary	unspecified	permanent, endoscopic	temporary, endoscopic	Other, endoscopic	n	%
malignant neoplasms		4		2	3		9	2.2
subarachnoid haemorrhage	1	5		2	1		9	2.2
stroke, total	16	76	1	46	129	2	270	65.7
stroke, haemorrhagic	*2*	*2*		*2*	*6*		*12*	*2.9*
stroke, infarction	*6*	*7*		*7*	*14*		*34*	*8.3*
stroke, unspecified	*8*	*67*	*1*	*37*	*109*	*2*	*224*	*54.5*
other cerebrovascular disease	1	3		1	4		12	2.9
motor neurone disease	1	11		1	6		19	4.6
dysphagia, unspecified	1	57	1	5	26		90	21.9
other				1	4		2	0.5
Total	20	156	2	58	173	2	411	
	4.9%	38.0%	0.5%	14.1%	42.1%	0.5%		

78% of gastrostomies were carried out in patients aged 65 and over. 84% of stoke patients were aged 65 and over, and the median age of stroke gastrostomy patients was 76 (Table 3).

Hospital episode statistics do not record enteral feeding via nasogastric tubes, so the number of patients receiving nasogastric tube feeding is unknown.

Table 2: Gastrostomies, in-patient length of admission, West Midlands Hospital Episode Statistics 1996-1997

	Mean	Std. Deviation	Median	N	Minimum	Maximum
malignant neoplasms	43.9	29.3	39	9	5	107
Subarachnoid haemorrhage	62.8	40.2	61	8	0	117
stroke, total	56.9	47.4	46	261	0	382
motor neurone disease	45.7	22.2	42.5	18	5	99
dysphagia, unspecified	39.3	50.7	23.5	76	0	282
other	52.7	42.2	65.5	12	0	106
Total	52.5	46.9	43	384	0	382

Table 3: Gastrostomies, patients' age and diagnosis, West Midlands Hospital Episode Statistics 1996-1997

	Mean	Std. Deviation	Median	N	Minimum	Maximum
Malignant neoplasms	70.4	11.5	71	9	52	88
Subarachnoid haemorrhage	61.9	23.9	67	9	2	83
stroke, total	74.8	10.7	76	270	39	95
motor neurone disease	76.8	7.2	75	19	63	89
dysphagia, unspecified	64.6	21.0	71	90	4	92
other	68.6	20.2	69.5	14	14	93
Total	72.1	14.9	75	411	2	95

2.4 Outline of typical current alternative service

Nasogastric tube feeding has traditionally been used in stroke patients with a prospect of extended survival (>4 weeks) who are unable to maintain adequate oral nutrition and fluid balance. PEG feeding is increasingly used in this situation, and can be carried out in a home or nursing home setting by carers and staff. Nasogastric tubes may become dislodged or be removed by patients, so that replacement tubes are required. An audit of an acute geriatric assessment unit found that 139 out of 2332 patients (6%) required nasogastric feeding at some stage, and that an average of 12 tubes per intubated patient were used[17].

Although home nutritional support is becoming more common[18], most GPs will not have a patient on home enteral tube feeding using either method. The support available to the patient on discharge on hospital will vary. GPs can prescribe feeds, but not other items. Local financial and organisational arrangements are therefore critical to successful use of enteral feeding in community settings.

3 Questions addressed by this review

Is percutaneous endoscopy feeding more effective than nasogastric tube feeding in stroke patients requiring enteral feeding with regard to mortality, morbidity and health related quality of life?

4 Methods

4.1 Search strategy

Reviews and primary studies were identified in the following databases:
Medline, Science Citation Index, Embase, DARE, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register, ISI Conference Proceedings and Transcripts. Searches were conducted in July 1998.

The following searches (adapted for each platform) were used:
1. (*percutaneous adjacent endoscopic adjacent gastrostomy* as text) or (*peg* as text) or (*gastrostomy* as MESH term or text) or *enteral nutrition* as MESH term or text) or (*surgery endoscopic* as MESH term or *endoscopic surgery* as text) or (*intubation, gastrointestinal* as MESH term or *gastrointestinal intubation* as text);
and
(*cerebral hemorrhage* as MESH term or text) or (*cerebrovascular disorders* as MESH term or text) or (*cerebral infarction* as MESH term or text)

2. (*cerebrovascular disorders* as MESH term or *stroke* as text) or (*cerebr$* as text));
and
(*feeding methods* as MESH term or *feeding* as text) or (*intubation, gastrointestinal* as MESH term or *enteral nutrition* as MESH term or *nasogastric* as text) or (*gastrostomy* as MESH term or text) or (*endoscopy, esophagoscopy, gastroscopy* as MESH terms or *endoscop$* as text).

The searches were inclusive, rather than restrictive, and reviews and primary studies with relevant subject matter were identified by inspection of titles and abstracts, obtaining papers where necessary.

Searches of the NEED and HTA databases and the National Research Register were made using each of the following text words, *stroke, feeding, gastrostomy, enteral, endoscop$* and *PEG*. The results were scanned for relevant studies.

Other sources included hand search of Drugs and Therapeutic Bulletin (1996 and 1997), follow-up of citations from reference lists and personal contacts.

4.2 Inclusion criteria for the evidence

4.2.1 Study design

A search was made for randomised control trials to compare the outcomes of PEG versus NGT.

Additionally a search was made for case studies of PEG to provide further information on procedure related mortality rates.

4.2.2 Study population

The study population was preferably stroke patients with persistent dysphagia requiring enteral feeding, but studies which included patients with dysphagia resulting from conditions other than stroke were included.

4.2.3 Intervention

PEG feeding compared with nasogastric tube feeding.

4.2.4 Outcome measures

It has been suggested that consideration of whether PEG should be used in preference to NGT depends upon its relative efficiency in terms of achieving adequate intake, nutritional indices, safety, patient tolerability, flexibility and ease of use, effects on other rehabilitation activities, duration of hospitalisation and costs[1]. Other possible outcomes include health related quality of life and mortality.

The outcomes considered here were: mortality and survival, procedure related mortality and complications, patient health related quality of life, patient and carer preferences, volume of food delivered.

RCTs that measured any of these outcomes were to be included.

4.3 Criteria for the evaluation of the evidence

Trials were to be evaluated in accordance with suggested guidelines[19] and important features of trial design, including blinding, randomisation, concealment of randomisation and reporting of drop-outs, crossovers and losses to follow-up[20], were recorded.

Caution was exercised where there were small effect sizes or conclusions based on small numbers of cases or sub group analyses, as such results generally need to be confirmed in further trials.

4.4 Data extraction

Data extraction of RCTs was carried out by CC and AB and differences were discussed and reconciled. Data extraction of case series was carried out by CC alone.

4.5 Economic analysis

A search was made for economic analyses of different methods of enteral feeding in stroke patients (see 5.1).

An assessment of the cost effectiveness of PEG compared to NGT feeding was carried out based on the evidence provided by the review.

5 Quality, direction and strength of the evidence

5.1 Randomised control trials

There have been three randomised trials of PEG versus nasogastric feeding[21,22,23] (Table 4). One trial (Baeten) is described as "not yet completed".

5.1.1 Quality, design and execution

Table 4 describes relevant aspects of trial design.

All of the trials were small.

In only one trial (Park)[21] was it clear what the primary hypothesis of the trial had been, and what the trial had been powered to detect.

The nature of the intervention (different methods of enteral feeding) made blinding of clinicians, other staff and patients and the blind assessment of outcomes impossible.

Randomisation was via sealed or “closed” envelopes.

Reporting of results was by intention to treat. In one trial (Park) [21], however, patient crossovers meant that there was only sparse and censored information on NGT feeding. Dropouts, crossovers and losses to follow-up were adequately reported.

In one study (Baeten) [23], it was unclear whether standard deviations or reference ranges are reported, so only mean values are quoted here. The duration of this trial was not stated, and survival data were not presented, making interpretation of the death data in the trial impossible.

5.1.2 Patients

Patients in the Park trial[21] had dysphagia of at least four weeks duration resulting from neurological conditions, were likely to survive for at least the trial duration and were able to communicate (Table 5).

Patients in the Baeten trial[22] had neurological, surgical or ENT indications for PEG and no preference for PEG or NGT.

Patients in the Norton trial [23] had dysphagia of at least eight days duration 14 days after an acute stroke and had been unconscious on hospital admission and were described as being in a stable condition. They were likely to have been sicker than the patients in the other two trials and at higher risk of death.

It was considered that the patient populations in the trials were so different that the trial results could not be pooled to produce summary estimates of the results.

5.1.3 Outcomes

5.1.3.1 Treatment success

In all three trials, treatment failure occurred more often with NGT than with PEG feeding (Table 6).

Patients were more likely to have the entire amount of their prescribed foods with PEG rather than NGT feeding[21,23]. PEG feeding was also associated with an increase in nutritional indices[21,23] (Table 6).

Table 4: Randomised control trials of NGT and PEG feeding, design, quality and execution

	Park RHR et al 1992[21]	Baeten C & Hoefnagels J 1992[23]	Norton B et al 1996[23]
Power calculation for study reported	Yes	No	No
Study was powered to:	Detect difference in treatment success of 40% with NGT and 90% with PEG, with power of .9 and statistical significance at p<.05		
Proportion of eligible patients randomised	Not given, some patients opted for PEG outside the study.	Of 200 eligible patients, 90 (45%) had no preference for NGT or PEG and no contraindication.	First 30 eligible patients recruited.
Method of randomisation	Numbered sealed envelopes.	Sealed envelopes, stratification by indication (neurologic, ENT, surgical)	Closed envelopes.
Blinding	None	None	None
Reporting of drop-outs	Yes. 1 patient in each arm died after randomisation but before receiving intervention. Treatment failure in 18 (95%) NGT group and 0 in PEG group.	Yes. Failure to introduce NGT 4 patients, later failure 8 patients, total failure 26%. Failure to introduce PEG 3 patients (7%)	Yes. 3 NGT treatment failures.
Reporting of cross-overs	18 (95%) of NGT group successfully switched to PEG.	6 NGT patients had a PEG on treatment failure	None reported.
Reporting of losses to follow-up	Yes	Yes	Follow-up lab data not available for 1 PEG and 4 NGT patients (deaths and drop-outs).

5.1.3.2 Mortality

The Norton trial[23] found a significant difference in mortality (Table 6) at 6 weeks in stroke patients with persistent dysphagia at 14 days post stroke who had PEG as opposed to NGT feeding, with a relative risk for PEG of 0.29 (p=.02, Fisher's exact test). The 6 week mortality of dysphagic stroke patients, however, is high[9], and the results cannot be applied to patients who remain dysphagic, do not die, and are therefore candidates for PEG feeding in a later stage of their disease. The patients had a mean Barthel Activites of Daily Living Index of <3 (maximum 100) at recruitment, indicating the patients had poor functional status and a poor prognosis. This is a small trial (n=30), and this finding needs confirmation in further studies

The Baeten trial[22] found a greater number of deaths in PEG patients than in NGT patients, but could offer no explanation for this finding. It was impossible to interpret this finding, as no indication was given of length of follow-up. The number of stroke patients included in the trial was not given, but must have been less than the 42 (47%) who had neurological conditions. The PEG procedure appeared to have contributed to one surgical patient's death: the needle for the introduction of the PEG had perforated the liver with subsequent intraperitoneal bleeding. The patient died of sepsis following anastomatic leakage follow rectal cancer resection.

In the Park trial[21], the only two deaths occurred post randomisation but prior to tube insertion. Patients in this study had neurological dysphagia of four or more weeks duration, were considered likely to survive at least for the duration of the trial. The trial therefore offers no evidence on the impact of PEG feeding compared to NGT feeding on mortality in patients with longstanding dysphagia.

5.1.3.3 Treatment acceptability

Two trials (Park, Baeten)[21 22] found that PEG was more acceptable to patients than NGT feeding (Table 6).

In one trial (Baeten), PEG was preferred by nursing staff and reduced patient fixation was required to prevent removal of tubes by patients[22].

5.1.3.4 Complications

Apart from the death in the Baeten[22] trial described above, which may have been related to the PEG procedure, there were only minor complications (Table 6). Two cases of aspiration pneumonia in the Park trial[21] were probably not related to the PEG feeding method.

5.1.3.5 Other outcomes

Two trials reported a small increase in weight with PEG feeding[21 23] and one reported an increase in serum albumin[23] in PEG patients. In two trials, more PEG than NGT patients were discharged[22 23] (Table 6). In one trial, PEG resulted in earlier discharge, probably because PEG was more acceptable to nursing homes than NGT feeding[23]

Table 5: Randomised trials of NGT and PEG feeding, patients

	Park RHR et al 1992[21]	Baeten C & Hoefnagels J 1992[22]	Norton B et al 1996[23]
Entry criteria	Dysphagia of duration >=4 weeks, neurological diseases, likely to survive >=1 month, able to communicate, normal gastrointestinal tract	Neurological, ENT and surgical indications, no patient preference for PEG or NGT	Persistent dysphagia (duration >=8 days) 14 days after acute stroke. All unconscious on admission, in stable condition, enteral feeding appropriate
Dysphagia definition	Neurological dysphagia	Not given	Absence of normal gag reflex/inability to swallow 50ml water easily without choking
Exclusion criteria	dementia, mechanical lesions, intra-abdominal inflammation, relevant adverse history, major systemic disease	NGT or PEG contraindicated. Patient preference	Gastrointestinal disease precluding siting of gastrostomy tube, unfit for upper GI endoscopy or intravenous sedation.
Setting	3 teaching hospitals	Academic hospital	One university hospital and one district general hospital
Number in trial	40 (18 cerebrovascular disease) 20 NGT, 20 PEG	90 (42 neurologic indication, 39 ENT indication, 9 surgical indication) NGT 46, PEG 44 Neurological indication: NGT 23, PEG 19	30 recruited over 1 year NGT 14, PEG 16
Patient characteristics	Mean age; NGT65 (se 2.9), PEG 56 (se 4.8) NGT 10F/10M PEG 12M/8F	Mean age 72 (neurologic indication 79), 62% male (45%, neurologic indication)	NGT: 4M, 10F, mean age 79 PEG: 7M, 9F, mean age 76 Mean Barthel Index at recruitment <3
Trial duration	28 days	Not given	6 weeks

Table 6: Randomised control trials of PEG and NGT, outcomes

	Park RHR et al 1992[21] (NGT 20, PEG 20)	Baeten C & Hoefnagels J 1992[22] (NGT 46, PEG 44)	Norton B et al 1996[23] (NGT 14, PEG 16)
Treatment failure	NGT 18 (95%)* PEG 0	NGT 26% (4 could not insert, problems:8/42, 4/21 neurological indications)* PEG 7% (3 could not insert)	NGT 3 (21%) (unable to resite 2, recurrent removal 1) PEG 0
N of tube insertions	12 patients displaced tube 3 times, 2 patients displaced tube twice	NGT mean 2.7 (underestimate) PEG 1	NGT mean 6 (range 1 to 10) PEG 1
Insertion time		NGT 8.4 minutes PEG 11.4 minutes	
Mortality		NGT 5/46 (4/23 neurological indication*) PEG 13/44 (11/19 neurological indication) (1 PEG related death)	NGT 8/14* PEG 2/16
Duration of feeding	NGT 5.2 (se 1.5) days* PEG 28 (se 0)	NGT 16.4 days PEG 21.6 days (in hospital)	
Feed intake	NGT had 55% (se 4) of prescribed food* PEG had 93% (se 2) of prescribed food		NGT 10 (71%) missed feeds waiting for resiting of tube, mean loss 22% (95% CI 6-37%) PEG no omitted feeds
Weight gain	After 1st week: NGT 0.6kg (se 0.1)* PEG 1.4kg (se 0.5)		NGT 1/8 gained weight, mean change -2.6kg* PEG 10/13 gained weight, mean change +2.2kg
Serum albumin concentration			NGT mean change (N=10) -9.5g/l* PEG mean change (N=15) +2.7g/l
Patient preference	PEG acceptability excellent (16), very good (21), fair (1) (includes crossovers)	PEG preferred NGT mean 2.3 (n=21) (1=very good) PEG mean 1.78 (n=22)	
Nurse preference		PEG preferred NGT mean 2.6 out of 5 (1=very convenient) PEG mean 2.0	
Patient fixation		NGT 10 (22%) PEG 3 (7%)	
Discharge rates		NGT 7 (7 neurological) PEG 11 (4 neurological)	At 6 weeks: NGT 0* PEG 6 (38%)
Complications	NGT none (but short duration of treatment) PEG 2 aspiration pneumonia, 1 minor infection	NGT clotting 15%, aspiration 7%, swallowing problem 17%, nasal decubitus 6% PEG clotting 16%, aspiration 3%, mild inflammation 27%, abdominal pain (<=3 days) 11%, abdominal bleeding 2%	PEG 1 peristomal infection
Natural history of dysphagia	3 stroke patients swallowing improved and PEG was removed		3 patients regained normal swallowing and had PEG tube removed.
* NGT vs PEG, P <.05			

5.2 Evidence from case series

Case studies were sought to provide information on any procedure related mortality associated with PEG insertion. A comprehensive search for case studies was not attempted, as it was considered that sufficient case series had been obtained to identify the range of procedure related mortality rates that were likely to be found in current practice. Studies which included patients who had open as well as endocopic gastrostomies, for example that of Ciocon[11], and some smaller studies have been excluded.

Table 7: PEG case series, patients

Study	Design	N	Subjects	Days between stroke and PEG insertion	Criteria for PEG insertion
Mamel [24]	review, including local case series	1.338 (327 local)	Not specified. Local series mostly neurological indications	not specified	
Raha et al[6]	case series	161	neurological dysphagia 88% (stroke 81%), nutritional support 12%	mean 44 (6-200)	
Wanklyn et al[25]	Retrospective	41	all stroke patients who had PG	median 26 days (12-131)	
Panos et al[15]	Prospective	76	76% neurological indications, 51% stroke		Impaired swallowing and nutritional need for enteral feeding expected to exceed 2 weeks. Inpatients: intolerant of NGT. Outpatients: opted for PEG
Hull et al[2]	Prospective	49	referred dysphagic patients (33% stroke)		referred patients
Larson et al[26]	Retrospective	314	75% neurological indications		referred for PEG
Kaw et al[7]	Retrospective	46	nursing home residents, 24% stroke (2 thirds coma), 52% dementia		
Finucane et al[17]	Retrospective	28	dysphagic patients (26 stroke)	mean 63 (6-210)	

Table 8 PEG case series, outcomes

Study	Duration of follow-up (range)	Results	Comments
Mamel [24]	not specified	Complications 14%, 30 day mortality 9-15%	
Raha et al[6]	mean 152 (11-106)	30 day mortality 20% (80% nutritional support), 90 day mortality 39%complications 12%, mostly minor, *1 PEG related death (<1%),* 16 patients had 18 tube replacements	19 tubes removed after mean of 199 days (45-365) as swallowing regained. PEG preferred by patients
Wanklyn et al[24]	median 53 days (2-528)	Complications 30% (11 cases) 5 chest infections 3 local infections, 2 tubes removed, 1 perforation. *3 deaths from complications (2%).* 6 survivors assessed : 1 good functional outcome, mean Barthel index 7.	8 patients recovered safe swallowing at median of 30 days post PG.
Panos et al[15]	median 93 (3-785) days	Nursing time same for PEG (8 patients)as for NGT (12 patients) Weight, BMI arm circumference improved, PEG related mortality 4% (*1 PEG related death, 1 possibly PEG related,* 1 pneumonia death (PEG 5/12 duration) PEG related, 1 major complication, 25 minor complications.	Swallowing recovered in 16%, 26% mortality at one month
Hull et al[2]	mean 175 (30-560)	*1 death from peritonitis 11/12 after PEG (2%),* Long term complications 22% 51% patients had no complication 47% complications required hospital visit	8% 30 day mortality
Larson et al[26]	at least 45 patients >1 year	Placement 95%, mortality 1%, major complications 3%.minor complications 13%, 14% regained ability to eat	
Kaw et al[7]	mean 321 (2-520)	No improvements in functional status, no improvements in mean serum albumin, complications 35% (tube obstruction 30%, tube migration 17%), aspiration pneumonia in 20%, survival 40% at 18 months	
Finucane et al[17]	median 98 in survivors, mean interval PEG and death 92 (6-200)	Successful in all patients, *1 PEG related death (4%),* 30 day mortality, 7%.	mean age 82 (range 66-99)

The case series found [2 6 7 15 17 24 25 26] confirm that there is some procedure related mortality attached to PEG, ranging from <1% to 4% in groups of patients that experience high mortality

rates from underlying condition. The 30 day mortality rates reported in these series vary from 7 to 26% and reflect the heterogeneous case mix of the PEG patients. The proportions of patients regaining swallowing function also reflects case mix and, where quoted, ranged from 12% to 20%.

5.3 Trials in progress

Two relevant randomised control trials are in progress and listed in the National Research Register, Issue 1 (http://www.doh.gov.uk/research/nrr.htm).

5.3.1 The FOOD multicentre RCT[27]

Patients: patients admitted with a stroke (excluding subarachnoid haemorrhage) within seven days of onset in whom the clinician is substantially uncertain about the best feeding policy.
Primary hypotheses: To assess whether nutritional supplementation increases the proportion surviving without disability.
To evaluate whether, in patients unable to take an adequate diet orally, the early initiation of tube feeding (NG or PEG) increases the proportion surviving without severe disability.
To assess whether a PEG tube instead of a NG tube, is associated with improved outcomes.

5.3.2 The PEGASUS multicentre RCT

Patients: inpatients with significant dysphagia unable to take adequate oral diet five days post stroke.
Primary hypothesis: To compare a policy of early PEG feeding versus initial conservative management (nasogastric or restricted oral feeding). The primary outcome measure is a modified Rankin scale incorporating death, and secondary outcomes are incidence of chest infections, length of stay, survival, discharge destination and Barthel ADL score at discharge.

These trials when completed should provide important evidence on the impact of PEG feeding in the early post stroke period on survival, functional status and other outcomes.

5.4 Summary: quality and direction of the evidence

- Three small non-blinded RCTs have compared NGT and PEG feeding.
- Two trials included some stroke patients, the third included solely stroke patients.
- The evidence indicates that PEG feeding is more efficient than NGT feeding and is more acceptable to patients who are able to express a preference.
- In one small trial[23], PEG feeding was associated with reduced risk of death of 0.3 at 6 weeks after insertion in patients who had persistent dysphagia at 14 days post stroke. This result requires confirmation in further RCTs.
- There is no useful evidence from randomised trials of the impact of PEG compared to NGT feeding on mortality in stroke patients with more longstanding dysphagia.
- The impact on longer term mortality and morbidity has not been adequately evaluated in RCTs.
- Some case series have reported procedure related mortality rates for PEG of up to 4%. One death in one of the trials[22] may have been related to the PEG procedure.
- Trials in progress will address some of the uncertainties around the benefits of enteral feeding in stroke patients and the use of PEG versus NGT in these patients.

6 Economic analysis

6.1 Economic literature

No economic analyses comparing PEG feeding with nasogastric feeding in stroke patients were found.

6.2 Economic analysis

6.2.1 Health consequences of NGT and PEG feeding

6.2.1.1 Process measures: food consumption

There is evidence that more food is consumed with PEG than with NGT[21 23]. It is possible that this may aid rehabilitation. However there is no evidence that the increase in food consumption leads to any significant improvement in rehabilitation.

6.2.1.2 Outcome of treatment: mortality

One small trial found that stroke patients fed with PEG had a reduction in mortality compared to NGT. However, PEG has not been shown to reduce mortality in dysphagic patients after the first 30 days. Evidence from case series suggests that there may be a risk of procedure related mortality.

6.2.1.3 Outcome of treatment: quality of life

There have been no formal evaluations of the effect on quality of life of PEG feeding in comparison to NGT feeding. Most patients who receive enteral feeding following stroke have poor functional status and a low quality of life. Any improvements in quality of life are therefore likely to be sufficiently small as to be undetectable on scales for the measurement of generic quality of life such as the EQ5D. There have been case reports illustrating the positive role which PEG feeding can play in the rehabilitation of a some stroke patients. In particular this has been when neurological damage apart from dysphagia is relatively limited. In these specific cases, quality of life gains may be more substantial[28 29].

Two trials[21 22] indicate a patient preference for PEG over NGT feeding: one in reported patient preferences, the other by patient crossover to PEG. This preference for PEG suggests that for the majority of patients subjective quality of life was better with PEG than NGT. As quality of life was not specifically measured, it is difficult to quantify this preference.

In two trials[22 23], more patients fed by PEG than by NGT were discharged from hospital. If these additional discharges could be attributed to PEG feeding, this suggests that patients fed by PEG may have a better functional outcome than those fed by NGT.

6.2.2 Health consequences: summary

Patients fed by PEG seem to have a slight improvement in their quality of life. It is not possible to quantify this in the context of their overall quality of life. There is no clear evidence that PEG offers advantages in terms of mortality, although more patients may be discharged from hospital. This must be offset against a small risk of procedure related mortality.

6.2.3 Resource consequences of NGT and PEG feeding

Because NGT feeding is the alternative to PEG, the overall resource consequences of PEG should be compared to the overall resource consequences of NGT feeding. The cost perspective adopted is that of the NHS. Because a formal cost analysis of either PEG or NGT feeding has not been carried out, a number of estimates are presented below. The first estimate is based on the estimated additional resource use which results from carrying out NGT feeding or PEG feeding. Since some of the resources (endoscopy unit) used are available anyway, the marginal costs of using them are assumed to be zero. The costs of food have been ignored as these are likely to be the same for both NGT and PEG. This cost estimation therefore focuses on the additional financial cost and to the NHS and the additional staff time needed.

The second estimate is based on the notional costs of NGT insertion or PEG insertion. This uses the prices charged for a private procedure as an estimate of the total resource costs. While it is clearly better to include all the costs of a procedure, there is no guarantee that the price charged is an accurate reflection of the cost of the procedure.

Table 9: Resource consequences of NGT and PEG feeding.*

	NGT	**PEG**
Number of procedures per patient	NGT typically reinserted a further 1 or 2 times (possibly more)	Rarely needs to be inserted more than once
Staff time per procedure	20 minutes of staff time per NGT insertion (nurse or junior medical staff)	30 minutes each of consultant medical staff time and senior nurse time per PEG
Additional facilities per procedure	None (carried out in ward)	Use of endoscopy unit
Additional investigations per procedure	Chest x-ray	
Disposables per procedure	NGT and associated disposables	PEG catheter
Effect on other costs		Possibly reduced length of stay in hospital

* Cost estimates supplied by the Royal Wolverhampton Hospitals NHS Trust.

6.2.4 Identifying resource consequences

NGT insertion requires the use of 20 minutes of staff time (typically nurse or junior medical staff time). The procedure is carried out on the ward. Some disposables and the NGT itself are also needed. NGTs typically need to be reinserted. In one trial, a mean of 2.7 NGTs were used per patient, compared to a single one PEG catheter. The figure of 2.7 insertions is therefore used in this cost estimation although the use of as many as 12 nasogastric tubes has been reported elsewhere[17]. To carry out PEG requires the use of the endoscopy unit, consultant medical staff and nursing staff. About 30 minutes of staff and endoscopy unit time is needed. The PEG

catheter itself costs £41. The main resource implications to the health service of NGT and PEG feeding are listed in

Table 10: Evaluation of resource consequences of NGT and PEG feeding.*

	NGT	**PEG**
Staff time	Per NGT insertion: 20 minutes Per patient (x 2.7): 54 minutes	Per patient: 60 minutes
Additional investigations	Chest x-ray: £9.20 to £11 Per patient (x 2.7): £25 to £30	
Disposables	Nasogastric tube: £3.20 to £8.80 Per patient (x 2.7): £9 to £24 Disposables: £1 to £2 (est.) Per patient (x 2.7): £3 to £5	Cost of a PEG catheter: £41
Total	Financial cost: £36 to £59 Staff time (nursing or junior medical staff): 54 minutes	Financial cost: £41 Staff time (nursing & senior medical staff): 60 minutes

* Cost estimates supplied by the Royal Wolverhampton Hospitals NHS Trust.

6.2.5 Measuring resource consequences

In terms of staff time and financial costs to the NHS, there is little difference between the cost of NGT feeding and PEG feeding. (Table 10) NGT feeding is likely to be slightly less costly than PEG feeding because it can be inserted by less senior staff and because the PEG catheter is more costly than disposable nasogastric tubes.

This approach ignores the marginal costs associated with the use of the endoscopy unit and possible marginal savings associated with reduced length of stay in hospital. If the endoscopy unit is not in continuous use, the opportunity cost of additional use for PEG is likely to be low. Similarly, cost savings associated with reduced length of stay are only likely to be realised if hospital beds and hospital staff are redeployed.

Table 11: Prices charged for PEG insertion (West Midlands NHS Trusts)

	Day case	In-patient
Trust A	£582	£904
Trust B	£401	£753
Trust C (physician)	£170	£1295
Trust C (surgeon)	£276	£858

6.2.6 Prices of PEG insertion

Table 11 shows the prices charged by trusts for PEG insertion. These vary widely from one trust to another and range from £170 to £1295. Unfortunately, equivalent prices for NGT insertion are not available. If junior medical and nursing staff time costs £15 an hour, we would expect NGT insertion costs to be in the region of £49 to £72. The resource costs of increased lengths of stay in patients fed by NGT are difficult to estimate. They are likely to be measured in hundreds rather than tens or thousands of pounds. By this method, it appears that the resource costs of PEG insertion feeding are much higher than those of NGT insertion but are likely to be offset by shorter lengths of stay.

6.2.7 Resource consequences - summary

The full economic costs of PEG feeding and NGT feeding are difficult to estimate. Prices charged are unlikely to be a true reflection of the economic costs.

In more practical terms, the financial and staffing implications of PEG feeding and NGT feeding are similar. The principal differences are that PEG insertion is carried out in an endoscopy unit, by consultant staff with senior nurses in attendance, whereas NGT insertions are carried out on the ward by ward nursing staff or junior medical staff.

6.3 Summary of economic analysis

The balance of evidence suggests that, compared to NGT feeding, PEG feeding is associated health gains. These include improved patient wellbeing and possibly earlier discharge. In practical terms, there are small differences in the resource implications of PEG compared to NGT. These are principally that PEG requires the use of more senior staff.

6.4 Implications for other parties

PEG is preferred to NGT feeding by nursing staff[6 15 22 23].

7 Conclusions

A small proportion of stroke patients will have persistent dysphagia. If enteral feeding is initiated, there is a choice of feeding via a PEG or a NG tube. Approximately 300 West Midlands stroke patients per year have a gastrostomy. The number having NGT feeding is unknown.

Although one small trial found that the early use of PEG feeding as opposed to NGT feeding was associated with a reduction in mortality in stroke patients, this result needs to be confirmed and cannot be generalised to patients where enteral feeding is initiated at a later stage.

Some case series have recorded a procedure related mortality of up to 4% for PEG in patient populations whose condition results in a high risk of death from other causes. One death in a patient who had not had a stroke in one trial[22] may have been related to the PEG procedure.

PEG feeding of dysphagic stroke patients appears to be associated with small improvements in wellbeing compared with NGT feeding in generally severely ill patients. The evidence for this improvement in wellbeing lies in patient preference for PEG over NGT in two small RCTs. For the vast majority of patients PEG feeding will have no impact on their functional status over and above that of NGT feeding.

Compared to NGT feeding, PEG feeding is associated health gains including improved patient wellbeing and possibly earlier discharge. There are small differences in the resource implications of PEG compared to NGT, principally that PEG requires the use of more senior staff.

Given the small resource difference and patient and nurse preference for PEG, the decision whether to use NGT or PEG feeding should be made by clinicians, carers and patients who should be aware that there have been procedure related deaths.

7.1 Areas of uncertainty

The costs of malnutrition in terms of skin breakdown and increased infections are high. Many stroke physicians believe that some kind of nutrition should be instituted by 7 to 10 days after stroke to prevent tissue and muscle breakdown. The impact of enteral feeding on malnutrition and its consequences, is, however, unclear[12] and has not been convincing addressed in the RCTs[21 22 23].

There is no evidence that adequately addresses the question of whether enteral feeding of dysphagic stroke patients has any impact on survival free of severe disability, and if so, whether PEG or NGT feeding is associated with improved outcomes.

The FOOD trial (which will not report until 2004) and the PEGASUS trial will address these issues.

7.2 Time limit for this report

The conclusions reported are likely to remain current until the above trials report.

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