Effect of timing and method of enteral tube feeding for dysphagic stroke patients (FOOD): a multicentre randomised controlled trial

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See Comment
See Article page 755

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Summary

Background Undernutrition is common in patients admitted with stroke. We aimed to establish whether the timing and route of enteral tube feeding after stroke affected patients' outcomes at 6 months.

Methods The FOOD trials consist of three pragmatic multicentre randomised controlled trials, two of which included dysphagic stroke patients. In one trial, patients enrolled within 7 days of admission were randomly allocated to early enteral tube feeding or no tube feeding for more than 7 days (early versus avoid). In the other, patients were allocated percutaneous endoscopic gastrostomy (PEG) or nasogastric feeding. The primary outcome was death or poor outcome at 6 months. Analysis was by intention to treat.

Findings Between Nov 1, 1996, and July 31, 2003, 859 patients were enrolled by 83 hospitals in 15 countries into the early versus avoid trial. Early tube feeding was associated with an absolute reduction in risk of death of 5·8% (95% CI –0·8 to 12·5, p=0·09) and a reduction in death or poor outcome of 1·2% (–4·2 to 6·6, p=0·7). In the PEG versus nasogastric tube trial, 321 patients were enrolled by 47 hospitals in 11 countries. PEG feeding was associated with an absolute increase in risk of death of 1·0% (–10·0 to 11·9, p=0·9) and an increased risk of death or poor outcome of 7·8% (0·0 to 15·5, p=0·05).

Interpretation Early tube feeding might reduce case fatality, but at the expense of increasing the proportion surviving with poor outcome. Our data do not support a policy of early initiation of PEG feeding in dysphagic stroke patients.

Introduction

Undernutrition is common in patients admitted with stroke, nutritional status can deteriorate in hospital, and undernutrition shortly after admission is independently associated with increased case fatality and poor functional status at 6 months.[1–7] To compound the problem, up to half of stroke patients in hospital have dysphagia, which precludes safe oral nutrition for the first few days and can persist for long periods.[8–10] Surveys of feeding practice after stroke have recorded much variation between hospitals in the UK, especially in the timing of the start of enteral tube feeding and whether a nasogastric or percutaneous endoscopic gastrostomy (PEG) tube is used.[11] Some clinicians delay tube feeding for 2 weeks or more. Although early nutrition is unlikely to be harmful, whether any nutritional benefits offset the difficulties and complications of initiating and maintaining early enteral tube feeding is unclear.

Moreover, difficulties with nasogastric feeding in stroke patients, who are often confused and uncooperative, has led to increasing use of PEG tubes at an early stage. Enthusiasm for this method has been encouraged by the results of a small single-centre randomised controlled trial[12] that reported much lower case fatality rates in patients fed via PEG (13%) rather than nasogastric tube (57%). If the timing or route of enteral tube feeding does affect outcome, the present variation in practice means that large numbers of patients are being denied best treatment. In the FOOD trials, which included two pragmatic randomised trials of dysphagic patients, we aimed to answer two main questions: (1) does early initiation of enteral tube feeding improve outcomes (early versus avoid trial); and (2) does enteral tube feeding via PEG rather than nastrogastric tube improve outcomes (PEG versus nasogastric trial)?

Methods

Trial design and participants

The FOOD trials consisted of three randomised controlled trials, which shared the same randomisation, data collection, and follow-up systems, and allowed co-enrolment. The two trials reported here enrolled patients with dysphagia. Eligibility criteria were broad: any patient admitted to a participating hospital with a recent (within 7 days before admission) stroke (first-ever or recurrent) could be enrolled if the responsible clinician was uncertain of the best feeding policy and the patient or a relative consented. Patients with subarachnoid haemorrhage were excluded. The FOOD trials were approved by the multicentre research ethics committee in the UK and by each centre's local research committee.

Procedures

Baseline data were acquired during a telephone call to the international coordinating centre at trial entry (table 1). Only when all baseline data had been entered and automatically checked did the computer give out a treatment allocation. Thus, baseline data were 100%

complete and treatment allocation was concealed until it was given. The randomising clinicians were also asked to confirm that consent had been obtained and to categorise patients as undernourished, normal, or overweight, on the basis of their own bedside assessment or, where practical, a fuller assessment that might include weight, height, dietary history, or blood tests.[7,13,14]

A computer-generated minimisation algorithm balanced treatments within each country, and used age (>75, <75 years), sex, and predicted probability of poor outcome (<80%, >80%) as stratification variables. The predicted probability was based on a well validated and reliable model consisting of six variables (age, prestroke independence, prestroke living alone, ability to lift both arms off the bed, ability to walk independently, and ability to talk without being confused).[15–18] The details of all enrolled patients were kept securely in our coordinating centre to allow proper intention-to-treat analysis.

In the early versus avoid trial, patients were allocated to start enteral tube feeding (via the clinician's preferred tube) as soon as possible or to avoid any enteral tube feeding for at least 7 days. Patients who were not tube fed were given parenteral fluids either intravenously or subcutaneously, but not nutrition. In the PEG versus nasogastric trial, patients were allocated to enteral tube feeding via PEG or nasogastric tube within 3 days of enrolment. The allocated method was continued as long as it remained practical, or as the patient's condition dictated. Patients in both groups of both trials were kept nil by mouth when the team felt this was necessary, but could be fed orally (instead of or in addition to tube feeding) if their swallowing ability improved. The randomising clinician, the clinical team, and the patients were not unaware to treatment allocation—doing so would have been impossible.

If the clinician was uncertain whether to start enteral tube feeding within 7 days of admission, the patient was enrolled into early versus avoid. The clinician could, if he or she wished, choose the type of tube. If during the first 30 days of admission the clinician was uncertain whether to insert a PEG or nasogastric tube (or to continue with an existing nasogastric tube), the patient could be enrolled into the PEG versus nasogastric trial. If the clinician was uncertain about both timing and type of tube feeding, patients could be co-enrolled at the same time (ie, if allocated early feeding the patient was randomly allocated to PEG or nasogastric tube) or at different times (eg, enrolled into PEG versus nasogastric trial after the end of the 7-day period of avoiding tube feeding in early versus avoid trial).

After discharge or in-hospital death, the local coordinator completed a hospital discharge form and, on the basis of a review of the case notes, recorded the start and finish dates of any enteral tube feeding or parenteral fluids, the route of enteral feeding, the number of tubes inserted, the types of food given, whether the clinician felt that enteral feeding had been satisfactory, the reasons for stopping, and any complications of feeding or of stroke. They recorded only complications that occurred after randomisation and before discharge or in-hospital death. This review was not explicitly done unaware of baseline nutritional status or treatment allocation. Data were audited centrally to check for completeness and internal consistency, and to ensure that they conformed to expected values and distributions.

	Early tube	Avoid tube	PEG tube	Nasogastric tube
Randomly allocated	429	430	162	159
Male	195 (45%)	199 (46%)	73 (45%)	71 (45%)
Age (years) (mean, SD)	76 (11)	76 (11)	76 (10)	76 (10)
Independent ADL before stroke	354 (83%)	358 (83%)	135 (83%)	126 (79%)
Lived alone	112 (26%)	120 (28%)	57 (35%)	50 (31%)
Can lift both arms	75 (17%)	63 (15%)	24 (15%)	27 (17%)
Walks unaided	16 (4%)	11 (3%)	4 (2%)	6 (4%)
Glasgow coma scale verbal normal	112 (26%)	117 (27%)	40 (25%)	40 (25%)
Predicted poor outcome*				
Mildest tertile	152 (35%)	140 (33%)	49 (30%)	48 (30%)
Moderate tertile	145 (34%)	142 (33%)	59 (35%)	59 (37%)
Most severe tertile	132 (31%)	148 (34%)	54 (33%)	52 (33%)
Baseline nutritional status				
Undernourished	34 (8%)	40 (9%)	36 (22%)	34 (21%)
Normal	313 (73%)	308 (72%)	96 (59%)	100 (63%)
Overweight	82 (19%)	82 (19%)	30 (19%)	25 (16%)
Country (four most common)				
UK	235 (55%)	233 (54%)	130 (80%)	130 (82%)
Italy	64 (15%)	65 (15%)	..	..
New Zealand	37 (9%)	34 (8%)	6 (4%)	3 (2%)
Singapore	34 (8%)	33 (8%)	9 (6%)	8 (5%)
Czech Republic	..	..	7 (4%)	5 (3%)
Diagnosis†				
Confirmed stroke	427 (>99%)	426 (>99%)	162 (>99%)	159 (>99%)
Brain tumour	1 (<1%)	1 (<1%)		
Other non-stroke	1 (<1%)	1 (<1%)		
Delay from stroke to randomisation‡	2 (1–4)	3 (1–4)	8 (4–13)	7 (5–12)
Delay from admission to randomisation‡	2 (1–4)	2 (1–4)	8 (4–13)	7 (4–12)

Data are number (%) unless otherwise indicated. ADL=activities of daily living. *Based on validated statistical model with six variables. †Final diagnosis of prerandomisation event recorded on hospital discharge form. ‡Median (IQR). Forms received for 429 patients in early tube group, and 428 in no tube group. Discharge forms received for all other patients.

Table 1: **Baseline characteristics of patients**

Follow-up aimed to establish patients' vital status, functional ability with the modified Rankin score (MRS),[19] place of residence, method of feeding, and quality of life with the EUROQoL.[20] The MRS grades patients from grade 0 (no symptoms) to grade 5 (requiring constant attention day and night). Each national coordinating centre obtained follow-up information 6 months after enrolment, mainly masked to treatment allocation, usually by means of a postal questionnaire or structured telephone interview. If patients were unable to provide information, it was acquired from a carer or proxy. Some patients in Singapore and India were followed up in an outpatient clinic or at home by a masked assessor. Thus follow-up was masked to treatment allocation (except where patients or carers inadvertently unmasked an interviewer at follow-up; such occurrences were unusual but their frequency was not systematically recorded).

Sample size calculations were based on a dichotomous outcome, dead or poor outcome at follow-up. The cut-off

value for poor outcome was MRS grade 4–5 in these trials, compared with grade 3–5 in our other trial,[13] because a grade of 3 in a dysphagic patient would be regarded as a good outcome in view of the associated severity of stroke. Our two primary outcomes were death or poor outcome and overall survival, subdivided by allocated treatment, irrespective of compliance.

Other outcomes, which were obtained masked to treatment allocation, included place of residence and EUROQoL score (from which a utility score was derived[21]). Other secondary outcomes that were not obtained masked to allocation were compliance with treatment, length of hospital stay, and in-hospital complications and causes of death. We planned to examine treatment effects on our primary outcomes subdivided by baseline nutritional status, baseline prognosis, and (in the PEG versus nasogastric trial only) time between stroke onset and randomisation. We also examined treatment effect by age at enrolment.

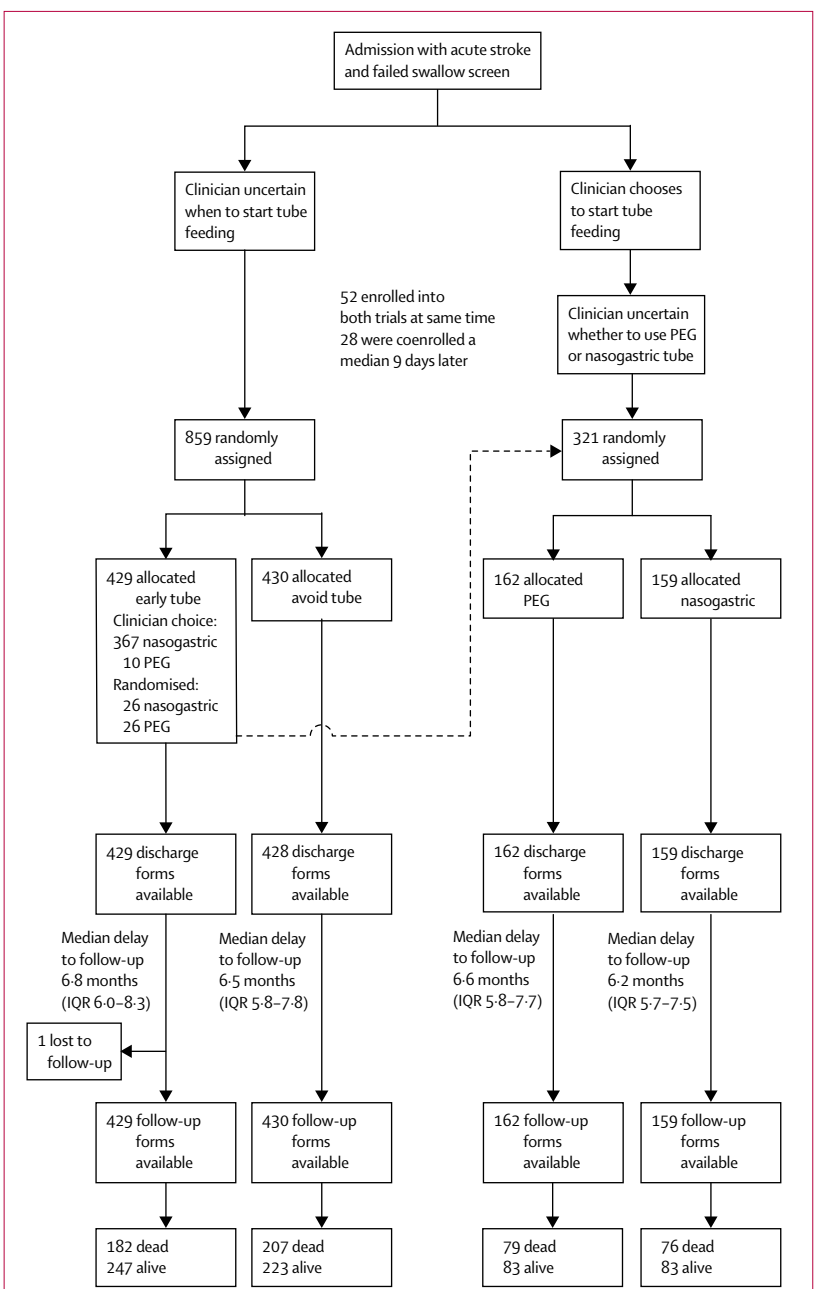

Figure 1: **Trial profiles**

The steering committee decided to stop the trials before we had reached our targets because no funding was available to continue beyond 2004 and they wished to ensure that the trials were closed in an orderly manner. Our decision to stop was not based on any knowledge of any interim analysis—indeed the data monitoring committee had recommended continuation if at all possible.

Centres were not paid to participate, and most did so without any financial support. We provided some UK centres that were allocating many patients with modest resources to help with enrolment and completion of discharge forms. National coordinating centres were given enough resources to cover their expenses—eg, telephone calls, travel, and stationery. From time to time, we ran recruitment drives during which we offered modest prizes (support to travel to a coordinators' meeting or a contribution to ward funds) to centres that recruited most patients by a particular time.

Statistical methods

We aimed to recruit 2000 patients in the early versus avoid trial, which would have provided 81% power to detect an absolute risk difference of 6% (p=0·05, two-sided) if 64% in the early group and 70% in the avoid group were dead or had a poor outcome (MRS 4–5). We planned to enrol 1000 patients in the PEG versus nasogastric trial, which would have provided 85% power to detect an absolute risk difference of 9% (p=0·05, two-sided) if 61% allocated PEG and 70% allocated nasogastric tube were to die or have a poor

outcome (MRS 4–5). Primary analyses were by intention to treat. The proportions of patients in each group with a dichotomous outcome (eg, who were dead or had a poor outcome) were compared with odds ratios and 95% CIs derived from unadjusted logistic regression. For death and in-hospital complications, Kaplan-Meier survival curves were constructed and the significance of any differences assessed with the log-rank test. Utilities derived from EUROQoL were compared with the Wilcoxon two-sample test. We calculated p values for subgroup analyses from the change in log likelihood when the interaction between treatment and subgroup of interest was entered into a logistic regression model.

Role of the funding source

The sponsors had no role in study design, data collection, data analysis, data interpretation, or writing the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Nov 1, 1996, and July 31, 2003, 83 hospitals in 15 countries enrolled 859 patients in the early versus avoid trial (participating centres and numbers of patients enrolled listed at end of report). 47 hospitals in 11 countries enrolled 321 patients in the PEG versus nasogastric trial; 80 (25%) had also been co-enrolled in the other trial, 52 at the same time (figure 1). Data about compliance, in-hospital complications, and follow-up were obtained until March 31, 2004, when the database was closed. Table 1 shows patients' baseline characteristics.

Baseline data were 100% complete. Discharge forms and follow-up forms were available for more than 99% of patients enrolled. Figure 1 shows the flow of patients through the trial. A few patients did not receive the allocated treatment for several reasons: inability to insert tubes, change of mind by clinicians or patients, logistic problems accessing PEG insertion within the 3 days specified in the protocol, administrative mistakes, and poor communication.

In the early versus avoid trial, of the 430 patients allocated to avoid tube feeding, 58 (13%) received tube feeding within 7 days of randomisation. Of the 429 patients allocated early tube feeding, 60 (14%) did not receive a tube within 3 days. In the PEG versus nasogastric trial, of 159 patients allocated nasogastric tube, 137 (86%) received this treatment (including 44 who were later swapped to a PEG tube). Of the others, nine received no tube feeding, and 13 received only PEG tube feeding. Only this last group are strictly cross-overs to the other treatment. Of the 162 patients allocated PEG tube, 78 (48%) received this tube within 3 days, and 115 (71%) received this tube before any nasogastric tube. Of the others, 21 received neither nasogastric nor PEG tube feeding, 17 received a nasogastric then a PEG tube, and nine received only nasogastric tube feeding. Only these last two groups are strictly cross-overs to the other treatment.

Figure 2 shows the proportion of patients starting their allocated feeding regimen during the first month after randomisation. Figure 3 shows the proportions receiving enteral feeding via a nasogastric or PEG tube while in hospital, the proportions receiving neither (ie, oral diet or parenteral fluids only), the proportion who had been discharged or had died during the first 6 months after randomisation in each group of the two trials. Any differences in outcomes should be attributable to the differences between these patterns of feeding. The numbers and proportion of enrolled patients who died and the MRS of survivors in each group are shown in table 2 and figure 4. Survival did not differ significantly between the treatment groups, although the early versus avoid curves seem to diverge at about 2 months after enrolment (log-rank test p=0·14; figure 5).

In the early versus avoid trial, allocation to early tube feeding was associated with a non-significant reduction in absolute risk of death of 5·8% (95% CI –0·8 to 12·5, p=0·09). The absolute reduction in risk of death or poor outcome was in the same direction but much more modest (1·2%, –4·2 to 6·6, p=0·7). In the PEG versus nasogastric trial, allocation to PEG feeding was associated with a non-significant increase in the absolute risk of death of 1·0% (–10·0 to 11·9, p=0·9) but an increase of borderline significance in absolute risk of

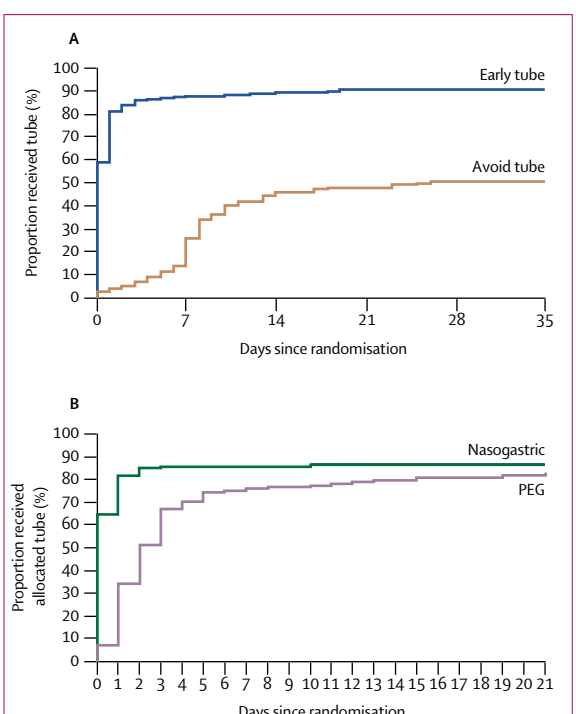

Figure 2: **Allocated and received method of feeding during first month after randomisation**
(A) early versus avoid and (B) PEG versus nasogastric trial.

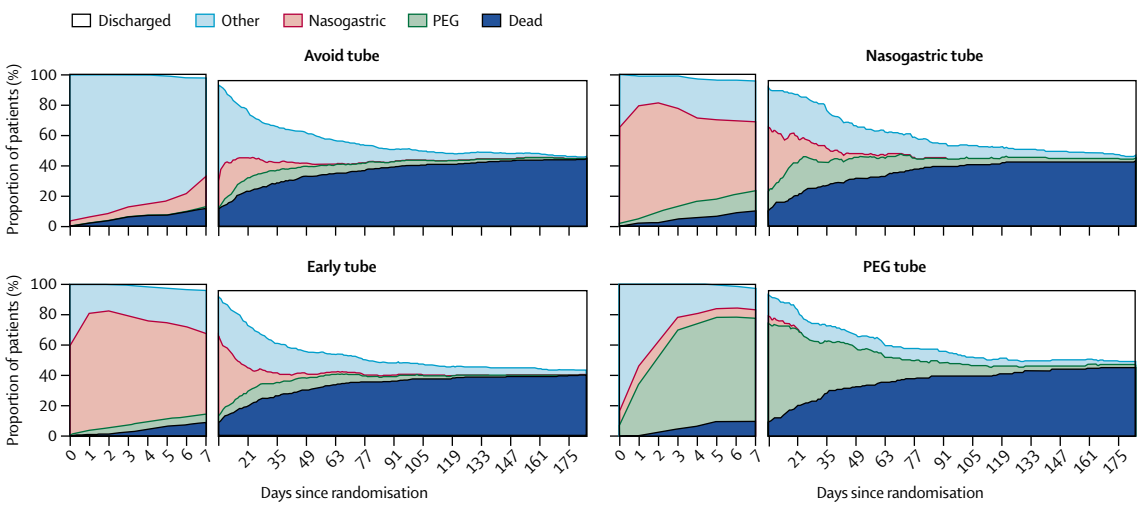

Figure 3: **Type of enteral tube feeding or other regimen (none, parenteral fluids, or oral), discharge, and death**
Death after discharge included but not proportion receiving tube feeding after discharge.

death or poor outcome of 7·8% (0·0% to 15·5%, p=0·05).

Of the 389 deaths in early versus avoid trial, 12 were attributed to tube feeding. Of these, five were in the avoid group, of whom three died after nasogastric insertion and two after PEG insertion. Of the seven in the early group, five died after nasogastric insertion and two after PEG insertion. In the PEG versus nasogastric trial, three of 76 deaths in the nasogastric group and eight of 79 in the PEG group were attributed to treatment.

In neither trial were there significant differences between groups in the frequency of recurrent strokes, neurological worsening, pneumonia, urinary infection, or venous thromboembolism. However, the rate of gastrointestinal haemorrhage was higher with early rather than avoid tube feeding (22 *vs* 11, p=0·04) and with nasogastric rather than PEG tubes (18 *vs* five, p=0·005). Not all these haemorrhages occurred while the tube was in place. Of the 33 haemorrhages in the early versus avoid trial, 19 occurred with a nasogastric tube in place, four with a PEG tube in place, six after removal of a nasogastric tube, two after removal of a

Modified Rankin Scale	Early tube (n=429)	Avoid tube (n=430)	PEG tube (n=162)	Nasogastric tube (n=159)
0	4 (1%)	9 (2%)	2 (1%)	1 (1%)
1	10 (2%)	16 (4%)	0	3 (2%)
2	26 (6%)	19 (4%)	7 (4%)	6 (4%)
3	50 (12%)	41 (10%)	9 (6%)	20 (13%)
4	53 (12%)	42 (10%)	8 (5%)	12 (8%)
5	104 (24%)	95 (22%)	57 (35%)	41 (26%)
Dead	182 (42%)	207 (48%)	79 (49%)	76 (48%)
Unknown	0	1 (<1%)	0	0
MRS 0–3	90 (21%)	85 (20%)	18 (11%)	30 (19%)
MRS 4–5	157 (37%)	137 (32%)	65 (40%)	53 (33%)
Dead or MRS 4–5	339 (79%)	344 (80%)	144 (89%)	129 (81%)

Table 2: **MRS score, primary outcome, and death**

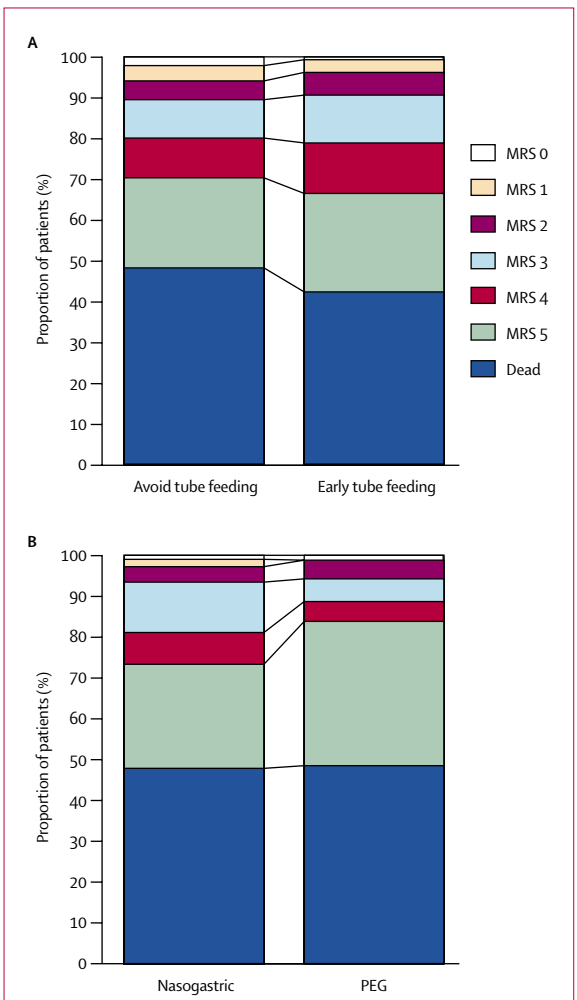

Figure 4: **MRS at follow-up**

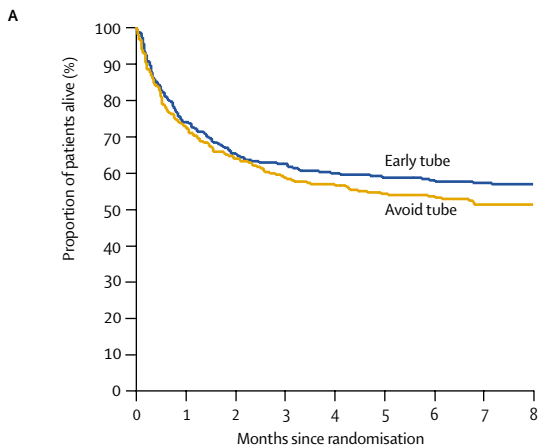

Figure 5: **Kaplan-Meier survival curves**
(A) early versus avoid and (B) PEG versus nasogastric tube.

PEG tube, and two in patients who never had a tube. Of the 23 haemorrhages in the PEG versus nasogastric trial, seven occurred during nasogastric feeding, ten during PEG, four after nasogastric removal, and two in patients without tubes. Data about the results of investigations of patients with gastrointestinal haemorrhage were not acquired systematically. There were more pressure sores in the PEG than nasogastric group (12 *vs* four, p=0·04). However, these data on complications need to be interpreted with caution because allocated treatment was not masked, many statistical comparisons were made, and it was not feasible for local source data to be verified for the occurrence of complications.

In the early versus avoid trial, discharge information was available for 429 (100%) in the early group and 428 (99·5%) in the avoid group; the median lengths of hospital stay were 24 days in both avoid (IQR 12–58) and early (IQR 12–53) groups. The mean length of stay was 45 days (SD 58) in the early group and 44 days (SD 50) in the avoid group (difference of means 1·3 days, –8·6 to 5·9). In the PEG versus nasogastric trial, discharge information was available for all patients. The median lengths of stay were 34 days (IQR 17–66) in the PEG group and 37 days (17–76) in the nasogastric group. The mean lengths of stay were 55 days (SD 68) and 53 days (SD 52), respectively (difference of means –2·1 days, 95% CI –15·5 to 11·3). There were no significant differences in the discharge destinations between the two groups in either trial.

Data for accommodation and feeding method at 6 months' follow-up were available for all but one patient in the avoid group (table 3). In the early versus avoid trial, follow-up data about quality of life (EUROQoL) were available for 421 (98%) in the early group and 428 (>99%) in the avoid group. Median utilities (including dead patients with a utility of 0) were 0·00 in both groups (p=0·76, difference in means 0·013, –0·028 to 0·053), but if dead patients were excluded, the utilities were marginally better for patients in the avoid rather than early feeding group (0·15 *vs* 0·08, p=0·35). In the PEG versus nasogastric tube trial, data were available in all but one patient (99%) in each group. If dead patients were excluded, median utility was 0·00 for both groups (p=0·12, difference of means 0·035, 95% CI –0·024 to 0·093), but when dead patients were excluded the utility was marginally better in the nasogastric group (0·08 *vs* –0·04, p=0·17).

Figure 6 shows primary outcomes by age, baseline nutritional status, tertiles of predicted stroke outcome, and time between stroke onset and randomisation (early randomisation defined as within 7 days of stroke onset in the PEG versus nasogastric trial). No differences were apparent in treatment effects between subgroups.

Discussion

We have not shown any significant differences in outcomes between early enteral tube feeding and avoidance of it. Nonetheless, there was an absolute difference in the risk of death in favour of early feeding, and although this was not significant at the 5% level, the CIs were precise enough that a clinically significant hazard from early tube feeding is unlikely. There was also no excess of pneumonia associated with early tube feeding, which will reassure many clinicians. However, the apparently improved survival was offset by the 4·7%

	Early tube feeding (n=429)	Avoid tube feeding (n=430)	PEG tube (n=162)	Nasogastric tube (n=159)
Living at home	153 (36%)	136 (32%)	35 (22%)	40 (25%)
Living in institution	94 (22%)	86 (20%)	48 (30%)	43 (27%)
PEG tube in place	30 (7%)	23 (5%)	34 (21%)	19 (12%)
Nasogastric tube in place	14 (3%)	10 (2%)	2 (1%)	3 (2%)

Table 3: **Accommodation and feeding at 6 months' follow-up**

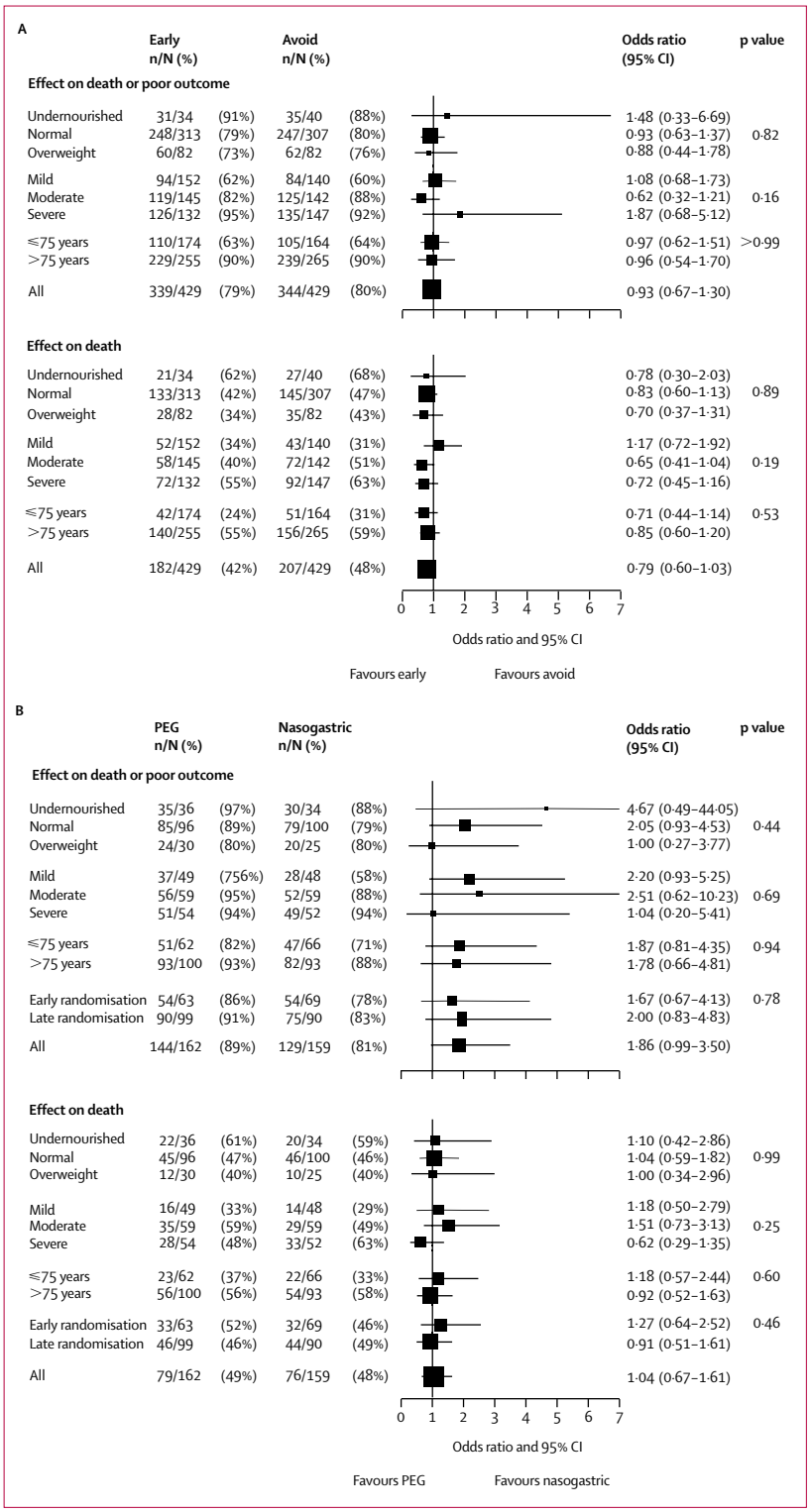

Figure 6: **Effect of (A) early tube feeding versus avoid tube feeding and (B) feeding via PEG versus nasogastric tube on both primary outcomes by baseline characteristics**

excess of survivors with a poor outcome, with worse quality of life in those allocated early tube feeding. Thus, early feeding may keep patients alive but in a severely disabled state when they would otherwise have died.

In our second trial, PEG versus nasogastric tube, there was an absolute difference in death or poor outcome in favour of nasogastric feeding. The CIs were precise enough that a clinically significant benefit from PEG rather than nasogastric tube feeding is highly unlikely. The explanation for this difference is not clear, but one factor might be the effect of a long-term PEG tube on dependency, since more patients in the PEG group were still receiving such tube feeding than in the nasogastric group at follow-up. The survivors in the PEG group were also more likely to be living in institutions and had lower quality of life. Worse outcomes might in part be explained by the greater delay to first tube feeding in the PEG group than in the nasogastric group, but the results from the early versus avoid trial suggest that this would be only a minor factor, assuming that the results of one trial apply to the slightly different population enrolled in the other.

One interesting finding in both trials was the greater risk of gastrointestinal haemorrhage in those who were tube fed, and especially those fed via a nasogastric tube. This might plausibly result from direct trauma to the gastric mucosa or from aspirin being put down the tube, but we had insufficient data to explore the mechanism further. Another intriguing finding was the excess of pressure sores in the PEG group, raising the possibility that those with such tubes might move less or be nursed differently.

One of this study's strengths is that it had a fairly large sample size. It is the first trial to assess the effect of early enteral tube feeding after stroke, and is only the third trial comparing PEG and nasogastric feeding after stroke.[12,22] It was ten times larger than any previous trial comparing these feeding methods in stroke patients.[12] Other strengths include recruitment from a wide range of hospitals in many countries, increasing generalisability; secure central randomisation with concealment of allocation; assessment of primary outcomes unaware of treatment allocation; almost 100% complete follow-up at 6 months. Weaknesses include insufficient statistical power to exclude more modest differences between groups; no information about the proportion of eligible patients enrolled in each centre; our use of an informal (although reliable and highly predictive) assessment of nutritional status; absence of precise monitoring of patients' daily intake of nutrients; absence of on-site source data verification or collection of information on changing nutritional status (eg, in-hospital weights); possible bias due to lack of masking of secondary outcome measures. Although compliance was not 100%, this fact results from the inevitable difficulties of adhering to rigid schedules when patients' conditions change after randomisation, of the preferences of clinicians, patients, and families for particular feeding regimens, and the practical and logistic problems of instituting and continuing enteral tube feeding.

There are no comparable trials assessing early tube feeding after stroke. However, a meta-analysis of the three completed trials comparing PEG and nasogastric tubes[22] estimates that the odds ratio for death is 0·88 (95% CI 0·59–1·33) in favour of PEG. This value is not significant, and the CIs are wide and include the possibility of a large advantage or disadvantage with respect to survival for PEG over nasogastric feeding. Heterogeneity was moderate (I^2=65%) between the three trials. Insufficient data were available to explore any other outcomes. It is unclear why the study by Norton and others[12] provided such an optimistic estimate of the benefits of PEG feeding; no baseline data were published, so chance imbalance in baseline severity of stroke within that trial resulting from the small sample size could be the explanation.

We think that further large randomised controlled trials addressing these issues are unlikely to be undertaken in the next few years. So how might these trials influence clinical practice? Our data would suggest that to reduce case fatality, unless there is a strong indication to delay enteral tube feeding (such indications would have excluded such patients from the FOOD trial), dysphagic stroke patients should be offered enteral tube feeding via a nasogastric tube within the first few days of admission. Also, for enteral feeding within the first 2 or 3 weeks, nasogastric feeding should be the chosen route unless there is a strong practical reason to choose PEG feeding (eg, the patient cannot tolerate a nasogastric tube).

FOOD Trial Coordination

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Independent Data Monitoring Committee—C J Bulpitt, A Grant (Chair), G Murray, P Sandercock.

National coordinators—N Anderson (New Zealand), S Bahar (Turkey), G Hankey (Australia), S Ricci (Italy).

Steering committee—G Bathgate, C Chalmers, G Cranswick, M S Dennis, B Farrell, J Forbes, S Ghosh, P Langhorne, S Lewis, J MacIntyre, C A McAteer, P O'Neill, J Potter, M Roberts, C Warlow.

Writing group—M S Dennis (Chair), S C Lewis, C Warlow.

FOOD trials collaboration by country (number of patients randomised in early versus avoid and PEG versus nasogastric trials, respectively)

Australia—Redcliffe Hospital (1,3): T Bennett, J Karrasch, C Lowe; The Alfred, Prahran (3,0): A Bramley, J Frayne; Royal North Shore Hospital, Sydney (1,0): E O'Brien, F Simpson.

Belgium—AZ Sint-Jan AV, Bruges (15,5): V Schotte, C Vandenbruaene, G T O Vanhooren, C Vanmaele.

Brazil—Hospital Universitario Fraga Filho, Rio de Janeiro (1,4): C Andre, M A S D Lima, M O Py.

Canada—Halifax Infirmary (2,0): S J Phillips, Y Reidy.

Czech Republic—District Hospital, Pardubice (14,12): E Ehler, P Geier, P Vyhnalek.

Denmark—Hvidovre Hospital (1,2): L Bech, D Rizzi, T Soerensen.

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Conflict of interest statement

The members of the writing committee declare that they have no conflict of interest.

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