

FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke

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Collaboration

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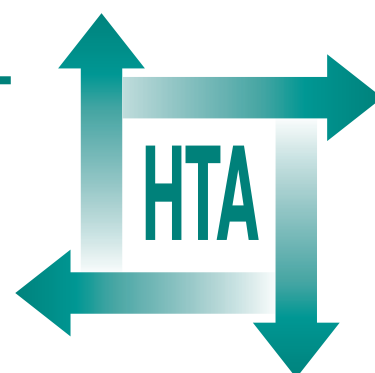
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Executive summary

Health Technology Assessment 2006; Vol. 10: No. 2

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

Objectives

Undernutrition is common among patients admitted to hospital with acute stroke. It may develop, or worsen, during hospitalisation, and is independently associated with poor outcomes. We aimed to answer three questions about feeding stroke patients in hospital:

1. Does routine oral nutritional supplementation of a normal hospital diet improve outcome after stroke?
2. Does early tube feeding improve the outcomes of dysphagic stroke patients?
3. Does tube feeding via a percutaneous endoscopic gastrostomy (PEG) result in better outcomes than that via a nasogastric tube (NG).

Design

The Feed Or Ordinary Diet (FOOD) trial was a family of three pragmatic, randomised controlled trials (RCTs). They shared facilities for randomisation, data collection, follow-up and coordination. Patients could be co-enrolled in more than one of these trials.

Setting

Patients were enrolled in 131 hospitals in 18 countries.

Participants

A total of 5033 patients who had been admitted to hospital with a recent stroke were enrolled in the trials between November 1996 and July 2003.

Interventions

In Trial 1, patients who could swallow within the first 30 days of admission were allocated to normal hospital diet versus normal hospital diet plus oral nutritional supplements (equivalent to 360 ml of 1.5 kcal/ml, 20 g of protein per day) until hospital discharge. In Trial 2, dysphagic patients enrolled

within 7 days of admission were allocated to early enteral tube feeding versus avoid any enteral tube feeding for at least 1 week. In Trial 3, dysphagic patients were allocated within 30 days of admission to receive enteral tube feeding via PEG versus NG.

Main outcome measures

The primary outcome was based on survival and the modified Rankin scale (MRS), a measure of functional outcome (grade 0 indicating no symptoms and grade 5 indicating severe disability, requiring help day and night). The primary outcomes were measured 6 months after enrolment, blind to treatment allocation, by the patient or their proxy completing a postal or telephone questionnaire.

Results

Trial 1: normal hospital diet versus normal hospital diet plus oral supplements

In all, 4023 patients were enrolled by 125 hospitals in 15 countries. This represents 67% of our original target of 6000 patients. Only 314 (7.8%) of patients were judged undernourished at baseline. Vital status and MRS at the end of the trial were known for 4012 (99.7%) and 4004 (99.5%), respectively. Of the 2007 allocated normal hospital diet, 253 (12.6%) died, 918 (45.7%) were alive with poor outcome (MRS 3–5) and 823 (41.1%) had a good outcome (MRS 0–2). Of the 2016 allocated oral supplements, 241 (12.0%) died, 953 (47.3%) were alive with poor outcome and 813 (40.4%) had a good outcome. The supplemented diet was associated with an absolute reduction in risk of death of 0.7% (95% CI –1.4 to 2.7; $p = 0.5$) and a 0.7% (95% CI –2.3 to 3.8, $p = 0.6$) increased risk of death or poor outcome.

Trial 2: early enteral tube feeding versus avoid enteral tube feeding

A total of 859 patients were enrolled by 83 hospitals in 15 countries, 43% of our original target of 2000. MRS at the end of the trial was known for 858 (99.9%). At follow-up, of 429 allocated early tube feeding, 182 (42.4%) died,

157 (36.6%) were alive with poor outcome (MRS 4–5) and 90 (21.0%) had a good outcome (MRS 0–3). Of 430 allocated avoid tube feeding 207 (48.1%) died, 137 (31.9%) were alive with poor outcome and 85 (19.8%) had a good outcome. 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% (95% CI –4.2 to 6.6; $p = 0.7$).

Trial 3: NG tube feeding versus PEG tube feeding

In this trial, 321 patients were enrolled by 47 hospitals in 11 countries, 32% of our original target of 1000 patients. Of 162 allocated PEG, 79 (48.8%) died, 65 (40.1%) were alive with poor outcome and 18 (11.1%) had good outcome. Of 159 allocated NG, 76 (47.8%) died, 53 (33.3%) were alive with poor outcome and 30 (18.9%) had good outcome. PEG was associated with an increase in absolute risk of death of 1.0% (95% CI –10.0 to 11.9; $p = 0.9$) and an increased risk of death or poor outcome of 7.8% (95% CI 0.0 to 15.5; $p = 0.05$).

Conclusions

Implications for healthcare

In Trial 1, we were unable to confirm the expected 4% absolute benefit for death or poor outcome from routine oral nutritional supplements. Our results would be compatible with oral supplementation being associated with a 1–2% absolute benefit or harm, but do not support routine supplementation of hospital diet for unselected stroke patients who are predominantly well nourished on admission.

In Trial 2, our data suggest that a policy of early tube feeding may substantially reduce the risk of dying after stroke and it is very unlikely that the alternative policy of avoiding early tube feeding would significantly improve survival. Improved survival may be at the expense of increasing the

proportion surviving with poor outcome. These data might usefully inform the difficult discussions about whether or not to feed a patient with a severe stroke.

In Trial 3, our data suggest that in the first 2–3 weeks after acute stroke, better functional outcomes result from feeding via NG tube than PEG tube, although we found no major difference in survival. These data do not support a policy of early initiation of PEG feeding in dysphagic stroke patients.

Recommendations for research

We think it is unlikely that the stroke community will have the ‘appetite’ for further and much larger RCTs assessing these interventions. This view is based on our surveys of clinicians’ views and the fact that avoiding tube feeding (Trial 2) and early PEG (Trial 3) are so unlikely to have a clinically significant benefit for patients.

Future research might be focused on making NG tube feeding safer and more effective by optimising methods of: insertion, confirmation of correct placement and retention of tubes. Also, studies need to confirm the increased risk of gastrointestinal haemorrhage associated with tube feeding and, if confirmed, establish whether any interventions might reduce this risk. Our finding that PEG tube feeding was associated with worse functional outcomes was unexpected and not easily explained. Future work might also aim to establish why these worse outcomes occurred in PEG-fed patients because patients with prolonged dysphagia or intolerance of an NG tube are inevitably fed via a PEG tube.

Publication

Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. *Health Technol Assess* 2006;**10**(2).

NHS R&D HTA Programme

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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.

Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.